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10 Attorneys for Plaintiffs
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13 **IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA**
 14 **IN AND FOR THE COUNTY OF SAN DIEGO**

15 EVELYN DADOUSH, a single individual;)	CASE NO.:
16 RICHARD KENNEDY, a single individual;)	
17 SARA KERBY, a single individual;)	COMPLAINT FOR DAMAGES
18 JOHNNIE KEY, a single individual;)	DEMAND FOR JURY TRIAL
19 GEORGE KRAINERT, a single individual;)	
20 ELIZABETH KRAMER, a single individual;)	Causes of Action:
21 MICHAEL KRAXBERGER, a single individual;)	(As to All Defendants)
22 KAREN KRUEGER, a single individual;)	1. Strict Products Liability – Design
23 OLGIERD KUBIAK, a single individual;)	Defect
24 VICKIE LANGSTON, a single individual;)	2. Strict Products Liability – Failure to
25 WENDI LAVALLEY, a single individual;)	Warn
26 JUDY LEAF, a single individual;)	3. Strict Liability in Tort
27 LILLIAN LEE, a single individual;)	4. Negligent Design
28 LOUIS LEE, a single individual;)	5. Negligence
JEFFREY LERNER, a single individual;)	6. Negligent Failure to Warn
KATHLEEN LESIAK, a single individual;)	7. Fraudulent Non-Disclosure
TIM LESSENDEN, a single individual;)	8. Negligent Misrepresentation
THOMAS LICKISS, a single individual;)	9. Fraudulent Misrepresentation and
ROBIN LINDSAY, a single individual;)	Concealment
KAREN LINEWAVER, a single individual;)	10. Negligence Per Se
LILLIE LOGAN, a single individual;)	11. Breach of Express Warranty
DOUGLAS LONG, a single individual;)	12. Breach of Implied Warranty
DANI LOWRY, a single individual;)	13. Deceit by Concealment – Violation
RONALD LUCAS, a single individual;)	

- 1 -

COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

1 - EXHIBIT A

1	BRUCE LUDWIG, a single individual;)	of California Civil Code §§ 1709, 1710
	TAMMY LUSK, a single individual;)	14. Violation of Business and
2	PATSY LYONS, a single individual;)	Professions Code § 17200
	LYNDA MACWHINNEY, a single individual;)	15. Violation of Business and
3	JULIA MALONE, a single individual;)	Professions Code § 17500
	DEBORAH SUE MANNO, a single individual;)	16. Violation of Civil Code § 1750, et
4	SHELIA MANTOOTH, a single individual;)	seq.
	LINDA MARINO, a single individual;)	(As to Innovator and Brand
5	RUTH MARSHALL, a single individual;)	Defendants)
	MICHAEL MARTZ, a single individual;)	17. Negligence
6	MARTHA MASON, a single individual;)	18. Fraudulent Non-Disclosure
	CLETUS MASTILOCK, a single individual;)	19. Negligent Misrepresentation
7	LINDA MATHIEU, a single individual;)	20. Fraudulent Misrepresentation and
	SCOTT MATLOCK, a single individual;)	Concealment
8	WILLIAM MCCANNA, a single individual;)	
9	RYAN MCCLEMENS, a single individual;)	
10	DOTTIE MCCLURE, a single individual;)	
	RAY MCCORD, a single individual;)	
11	THERESA MCCORD, a single individual;)	
	MICHELLE MCCORMICK, a single individual;)	
12	ANGELA MCCOY, a single individual;)	
	THOMAS MCCUNE, a single individual;)	
13	ALISON MCGHEE, a single individual;)	
	MAUREEN MCKAY, a single individual;)	
14	HAROLINE MCKENZIE, a single individual; and,)	
15	WASHINGTON MCLELLAND, a single)	
	individual;)	
16)	
	Plaintiffs,)	
17)	
18	vs.)	
)	
19	MCKESSON CORPORATION; ELI LILLY AND)	
	COMPANY; AAIPHARMA, INC; AAIPHARMA)	
20	LLC; AAI DEVELOPMENT SERVICES, INC.;)	
	NEOSAN PHARMACEUTICALS INC;)	
21	XANODYNE PHARMACEUTICALS, INC.;)	
	QUALITEST PHARMACEUTICALS, INC.;)	
22	VINTAGE PHARMACEUTICALS, INC.;)	
	PROPST DISTRIBUTION, INC.; BRENN)	
23	DISTRIBUTION, INC.; BRENN)	
24	MANUFACTURING, INC.; VINTAGE)	
	PHARMACEUTICALS, LLC;)	
25	GENERICS INTERNATIONAL (US), INC.;)	
26	GENERICS BIDCO I, LLC; GENERICS BIDCO)	
	II, LLC; GENERICS INTERNATIONAL (US)	
27	PARENT), INC.; ENDO PHARMACEUTICALS,)	
	INC.; ENDO PHARMACEUTICALS HOLDINGS)	
28	INC.; CORNERSTONE BIOPHARMA, INC.;)	

1 CORNERSTONE BIOPHARMA HOLDINGS,)
 2 INC.; TEVA BIOPHARMACEUTICALS, INC.;)
 3 TEVA PHARMACEUTICALS USA, INC.;)
 4 MYLAN PHARMACEUTICALS, INC.; MYLAN,)
 5 INC.; COVIDIEN PLC; COVIDIEN INC.;)
 6 MALLINCKRODT INC.; WATSON)
 7 PHARMACEUTICALS, INC.;)
 8 and DOES 1 through 50, inclusive,)
 9 Defendants.)

10 INTRODUCTION

11 1. This lawsuit concerns personal injury related to Plaintiffs' ingestion of prescription
 12 medication containing the active ingredient propoxyphene for treatment of mild to moderate pain,
 13 marketed and sold as generic and/or brand-name drugs under various names. All such medications
 14 that contain propoxyphene, in their various generic and brand-name forms, are referred to in this
 15 Complaint as "Propoxyphene Products".

16 2. Plaintiffs allege that Defendants MCKESSON CORPORATION; ELI LILLY AND
 17 COMPANY; AAIPHARMA, INC; AAIPHARMA LLC; AAI DEVELOPMENT SERVICES, INC.;
 18 NEOSAN PHARMACEUTICALS INC.; XANODYNE PHARMACEUTICALS, INC.;
 19 QUALITEST PHARMACEUTICALS, INC.; VINTAGE PHARMACEUTICALS, INC.; PROPST
 20 DISTRIBUTION, INC.; BRENN DISTRIBUTION, INC.; BRENN MANUFACTURING, INC.;
 21 VINTAGE PHARMACEUTICALS, LLC; GENERICS INTERNATIONAL (US), INC.; GENERICS
 22 BIDCO I, LLC; GENERICS BIDCO II, LLC; GENERICS INTERNATIONAL (US PARENT),
 23 INC.; ENDO PHARMACEUTICALS, INC.; ENDO PHARMACEUTICALS HOLDINGS INC.;
 24 CORNERSTONE BIOPHARMA, INC.; CORNERSTONE BIOPHARMA HOLDINGS, INC.;
 25 TEVA BIOPHARMACEUTICALS, INC.; TEVA PHARMACEUTICALS USA, INC.; MYLAN
 26 PHARMACEUTICALS, INC.; MYLAN, INC.; COVIDIEN PLC; COVIDIEN INC.;
 27 MALLINCKRODT INC.; WATSON PHARMACEUTICALS, INC.; and DOES 1 through 50,
 28 inclusive, inclusive knowingly or negligently manufactured, marketed, distributed, and sold
 defectively designed Propoxyphene Products without adequate warnings.

1 3. In July, 2009, the FDA ordered Defendant Xanodyne Pharmaceuticals, Inc.,
2 (hereinafter "Xanodyne") to make changes to the labels of its Propoxyphene Products. These
3 changes included: (a) an addition to the Clinical Pharmacology section of the label discussing the
4 cardiac effects of propoxyphene; (b) a revised boxed warning concerning the risks of both intentional
5 and accidental overdose; (c) the reiteration of this warning regarding the risk of overdose in the
6 Warnings section of the label; and (d) the addition of bolded warnings in the Dosage and
7 Administration section of the label warning against exceeding the maximum daily dose.

8 4. Without further discovery, it is unclear to Plaintiffs whether Xanodyne implemented
9 these required actions during the time that Propoxyphene Products remained on the market.

10 5. By ordering the RLD holder to make these changes to its label, the FDA empowered
11 Generic Manufacturer Defendants to make the same changes to their own product labels through the
12 "Changes Being Effected" (CBE) process that does not require prior FDA approval. 21 C.F.R.
13 §314.70(c). This is true whether or not Xanodyne ever implemented the labeling change.

14 6. The Generic Defendants could have made these labeling changes without running
15 afoul of the requirement of "sameness" because federal law expressly permits generic labeling to
16 differ from RLD labeling where the labeling revision is "made to comply with current FDA labeling
17 guidelines or other guidance." 21 C.F.R. §314.94(a)(8)(iv).

18 7. While Plaintiffs cannot know for certain without further discovery, it appears that
19 certain Generic Defendants never implemented these FDA-approved labeling changes between the
20 time that the FDA ordered the changes in July 2009 and the time that they withdrew Propoxyphene
21 Products from the market. Many of the Plaintiffs used and were injured by Propoxyphene Products
22 during this period and allege that their physicians would not have prescribed Propoxyphene Products
23 to them if they had been informed of these new warnings.

24 8. On information and belief, Defendant McKesson distributed Propoxyphene Products
25 with outdated and inaccurate labeling after July 2009, specifically, (a) an addition to the Clinical
26 Pharmacology section of the label discussing the cardiac effects of propoxyphene; (b) a revised
27 boxed warning concerning the risks of both intentional and accidental overdose; (c) the reiteration of
28 this warning regarding the risk of overdose in the Warnings section of the label; and (d) the addition

1 of bolded warnings in the Dosage and Administration section of the label warning against exceeding
2 the maximum daily dose.

3 9. On information and belief, Defendant McKesson, which distributes more
4 Propoxyphene Products throughout the United States than any other entity, is directly responsible for
5 distributing the Propoxyphene Products with outdated and inaccurate labeling ingested by multiple
6 Plaintiffs in this action.

7 10. Defendants knew or should have known that Propoxyphene Products were ineffective,
8 or at best, marginally effective, and that any benefits of propoxyphene were outweighed by its risks,
9 including serious risks of adverse cardiovascular events that could result in death, as well as other
10 injuries.

11 11. The serious health risks associated with Propoxyphene Products and the many safer
12 alternatives that were available led the British government to declare in a 2005 recall that it could not
13 identify *any* group of patients for whom the benefits of propoxyphene outweighed its risks.

14 12. In turn, in November 2010, the limited utility and significant risks associated with
15 Propoxyphene Products led the United States Food and Drug Administration ("FDA") to take action
16 to get all such products withdrawn from the market, and to get physicians to stop prescribing
17 Propoxyphene Products, but the FDA's actions came too late to prevent Plaintiffs' injuries.

18 13. All Defendants involved in the manufacture, marketing, distribution and sale of those
19 defectively designed drugs must be held liable for those injuries.

20 **PARTIES AND JURISDICTION**

21 14. Plaintiffs allege an amount in controversy above of the minimal jurisdictional limits of
22 this Court. A substantial part of the events giving rise to this claim occurred within the County of
23 San Diego, State of California. For example, Plaintiff Evelyn Dadoush, a citizen and resident of San
24 Diego County, was prescribed Darvocet and suffered injuries as a result, within San Diego County.

25 15. The true names or capacities, whether individual, corporate, or otherwise, of
26 Defendants DOES 1 through 50, inclusive, are unknown to Plaintiffs despite Plaintiffs' reasonable
27 attempts to identify Defendant DOES 1 through 50, who therefore sue said Defendants by such
28 fictitious names. Plaintiffs believe and allege that each of the Defendants designated herein by

1 fictitious names is in some manner legally responsible for the events and happenings herein referred
2 to and caused damages proximately and foreseeably to Plaintiffs as alleged herein.

3 16. At all times herein alleged, unless specified otherwise, "Defendants" include all herein
4 named Defendants as well as Defendants DOES 1 through 50, inclusive.

5 17. DOES 1 through 50, and each of them, acted independently of, or jointly with, other
6 Defendants, and are in some manner legally responsible for the events and happenings herein referred
7 to, and caused damages proximately and foreseeably to Plaintiffs as alleged herein.

8 **DISTRIBUTOR DEFENDANTS**

9 18. Defendant MCKESSON CORPORATION (hereinafter, "McKesson"), at all times
10 alleged herein, is and was a corporation organized and existing under the laws of the State of
11 Delaware, with its principal place of business in the city of San Francisco, County of San Francisco,
12 California, duly authorized to transact business in the State of California. At all times alleged herein,
13 McKesson is and was engaged in the business of marketing, distributing, promoting, advertising and
14 selling Propoxyphene Products nationwide and specifically within the State of California, including
15 San Diego County, where Plaintiffs resided and/or ingested Propoxyphene Products.

16 19. On information and belief, McKesson has been integrally involved in marketing,
17 promoting, distributing, advertising, and merchandising propoxyphene products, including
18 propoxyphene with inaccurate and outdated labeling, nationally, and specifically in the State of
19 California.

20 20. Upon information and belief and subject to discovery of information within the
21 exclusive control of Defendants, McKesson distributed the Propoxyphene Products ingested by
22 multiple Plaintiffs alleged herein to have ingested Propoxyphene Products. McKesson, maintains
23 comprehensive distribution agreements with major retail pharmacies including, but not limited to,
24 CVS, Wal-Mart, and Rite Aid.

25 21. The Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman
26 Amendments"), which amended the federal Food, Drug, and Cosmetic Act, does not address
27 distributor liability.
28

22. McKesson is not only one of the major national distributors of prescription drugs, it is also involved in several levels of marketing, advertising, and promoting products for its drug manufacturing clients.

23. On its website, McKesson announces that it delivers to pharmaceutical drug companies, "an unmatched combination of communication, promotion, distribution, and packaging options, plus targeted analytics of exclusive data. McKesson Manufacturing Marketing enables brands to set strategies that prioritize opportunities, optimize resources, and maximize profitability." McKesson further advertises in its National Consumer Outreach Campaigns, to:

[o]ffer bother pharmacists and manufacturers a high-profile public platform to increase awareness about a variety of health concerns, from general wellness to guidance on complying with specific therapies. McKesson works with manufacturers to tailor campaigns to their specific goals, and enhances the partnership between manufacturers and pharmacists to enhance the success of national consumer outreach campaigns.

Moreover, according to its website, McKesson builds "patient awareness through retail merchandising, promotions, and advertising," it increases "patient acquisition by fostering new trial usage," an enhances "pharmacists' brand awareness through multiple communication platforms, online ordering, and in-store promotions." McKesson advertises to pharmaceutical manufacturers, including those manufacturing propoxyphene, promising not only to deliver drugs, but once there,

[y]ou need help promoting your products, getting them on the right shelves, reducing out-of-stocks, and increasing your sales. Working with McKesson, we empower you to reach regional and independent pharmacies nationwide. And by supporting you with merchandising, front-end promotions, and other strategic programs, we help you grow your profits.

24. At all times alleged herein, McKesson includes any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their offices, directors, employees, agents, representatives and any and all other persons acting on their behalf.

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INNOVATOR AND BRAND DEFENDANTS

25. Defendant Eli Lilly and Company ("Eli Lilly") was at all relevant times a corporation organized under the laws of Indiana, with its principal place of business located at Lilly Corporate Center, Indianapolis, Indiana 46285.

26. Defendant, aaiPharma, Inc., ("aaiPharma") was at all relevant times a corporation organized under the laws of Delaware, with its principal place of business located at 2320 Scientific Park Drive, Wilmington, North Carolina 28405.

27. Defendant aaiPharma LLC ("aaiPharma LLC") was at all relevant times a limited liability company organized under the laws of Delaware, with its principal place of business located at 2320 Scientific Park Drive, Wilmington, North Carolina 28405.

28. Defendant AAI Development Services, Inc. ("AAI DS") was at all relevant times a corporation organized under the laws of Delaware, with its principal place of business located at 2320 Scientific Park Drive, Wilmington, North Carolina 28405. AAI DS was at all relevant times a division of aaiPharma.

29. Defendant NeoSan Pharmaceuticals Inc. ("NeoSan") was at all relevant times a corporation organized under the laws of Delaware, with its principal place of business located at 2320 Scientific Park Drive, Wilmington, North Carolina 28405. NeoSan was at all relevant times a commercialization business unit of aaiPharma.

30. Defendant's aaiPharma, aaiPharma LLC, AAI DS, and NeoSan shall be referred to herein individually by name or jointly as the "aaiPharma Entities."

31. Defendant Xanodyne Pharmaceuticals, Inc. ("Xanodyne") was at all relevant times a corporation organized under the laws of Delaware, with its principal place of business located at One Riverfront Place, Newport, Kentucky 41071.

32. For reference sake only, Defendant Eli Lilly, the Defendant aaiPharma Entities, and Defendant Xanodyne shall be referred to herein individually by name or jointly as the "Innovator and Brand Defendants," as these Defendants have, at various times as more fully set forth below, held the approved New Drug Application ("NDA") for Darvocet and Darvon, brand-name prescription

1 medications containing propoxyphene as their sole or primary active ingredient for treatment of mild
2 to moderate pain.

3 33. Upon information and belief, other entities besides Defendant Eli Lilly, the Defendant
4 aaiPharma Entities and Defendant Xanodyne, including but not limited to one or more other named
5 Defendants or other entities not yet named, were involved in the testing, manufacture, marketing,
6 sales and/or distribution of brand-name Propoxyphene Products, and to the extent such an entity has
7 done so, then such entity is also a "Innovator and Brand Defendant," although Plaintiffs are still in
8 the process of investigating the extent of such relationships.

9 34. Defendant Eli Lilly first introduced propoxyphene to the United States market in 1957,
10 and held the approved NDAs for Darvocet (propoxyphene) and Darvon (propoxyphene plus
11 acetaminophen) until 2002. Defendant Eli Lilly is credited as Innovator of both Darvon and
12 Darvocet.

13 35. In 2002, Defendant Eli Lilly sold its approved NDAs for Darvocet and Darvon to the
14 Defendant aaiPharma Entities, subject to numerous restrictions, as set forth below. Pursuant to this
15 agreement, Eli Lilly retained an ongoing role and interest in the manufacture and marketing of
16 Darvocet and Darvon, and on information and belief, Eli Lilly also continued to manufacture generic
17 propoxyphene products for certain generic drug companies.

18 36. In 2007, the Defendant aaiPharma Entities, as part of their bankruptcy reorganization,
19 sold their approved NDAs for Darvocet and Darvon to Defendant Xanodyne.

20 37. The Innovator and Brand Defendants were in the business of and did (either directly or
21 indirectly through subsidiaries, related entities, third parties, predecessors or successors in interest)
22 develop, design, research, test, license, manufacture, label, advertise, promote, market, sell, distribute
23 and introduce into interstate commerce throughout the United States, including in California and San
24 Diego County, Darvon and Darvocet for use as prescription pain management medications for mild to
25 moderate pain.

26 38. Upon information and belief, the Innovator and Brand Defendants entered into
27 contractual relationships related to the development, design, research, testing, licensing,
28 manufacturing, labeling, advertising, promotion, marketing, sale, distribution and/or introduction of

1 Darvon and Darvocet into interstate commerce throughout the United States, including within
2 California and San Diego County.

3 **GENERIC QUALITEST DEFENDANTS**

4 39. Defendant Qualitest Pharmaceuticals, Inc. ("Qualitest") was at all relevant times a
5 corporation organized under the laws of Alabama, with its principal place of business located at 130
6 Vintage Drive, Huntsville, Alabama 35811.

7 40. On or about November 7, 2007, Defendant Qualitest changed its name to Propst
8 Distribution, Inc. ("Propst"), but continued doing business under the name Qualitest Pharmaceuticals,
9 Inc.

10 41. Defendant Vintage Pharmaceuticals, Inc. ("Vintage") was at all relevant times a
11 corporation organized under the laws of Alabama, with its principal place of business located at 140
12 Vintage Drive, Huntsville Alabama 35811.

13 42. On or about November 5, 2007, Defendant Vintage changed its name to Propst
14 Distribution, Inc. ("Propst").

15 43. Defendant Propst was at all relevant times a corporation organized under the laws of
16 Alabama, with its principal place of business located at 130 Vintage Drive, Huntsville, Alabama
17 35811, and its reporting address located at 401 Meridian Street N, Huntsville, Alabama 35801.

18 44. On or about June 23, 2011, Defendant Qualitest and Defendant Propst changed their
19 legal names to Brenn Distribution, Inc. ("Brenn Distribution") and Defendant Vintage changed its
20 name to Brenn Manufacturing, Inc., but all continued doing business under the name Qualitest
21 Pharmaceuticals, Inc.

22 45. Defendant Brenn Distribution was at all relevant times a corporation organized under
23 the laws of Alabama, with its principle place of business located at 301 Meridian Street, Huntsville,
24 Alabama 35801.

25 46. Defendant, Brenn Manufacturing was at all relevant times a corporation organized
26 under the laws of Alabama, with its principle place of business located at 301 Meridian Street,
27 Huntsville, Alabama 35801.

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1 47. Defendant Vintage Pharmaceuticals, LLC ("Vintage LLC") was at all relevant times a
2 corporation organized under the laws of Delaware, with its principal place of business located at 130
3 Vintage Drive, Huntsville, Alabama 35811, and may have also done business under the name
4 Qualitest Pharmaceuticals.

5 48. Defendant Generics International (US), Inc. ("Generics US") was at all relevant times
6 a corporation organized under the laws of Delaware, with its principal place of business located at
7 130 Vintage Drive, Huntsville, Alabama 35811.

8 49. Defendant Generics Bidco I, LLC ("Generics Bidco I") was at all relevant times a
9 corporation organized under the laws of Delaware, with its principal place of business located at 130
10 Vintage Drive, Huntsville, Alabama 35811.

11 50. Defendant Generics Bidco II, LLC ("Generics Bidco II") was at all relevant times a
12 corporation organized under the laws of Delaware, which may have had its principal place of
13 business located at 130 Vintage Drive, Huntsville, Alabama 35811.

14 51. Defendant Generics International (US Parent), Inc. ("Generics US Parent") was at all
15 relevant times a corporation organized under the laws of Delaware, with its principal place of
16 business located at 130 Vintage Drive, Huntsville, Alabama 35811.

17 52. Defendant Endo Pharmaceuticals, Inc. ("Endo") was at all relevant times a corporation
18 organized under the laws of Delaware, with its principal place of business located at 100 Endo
19 Boulevard, Chadds Ford, Pennsylvania 19317.

20 53. Defendant Endo Pharmaceuticals Holdings Inc. ("Endo Holdings") was at all relevant
21 times a corporation organized under the laws of Delaware, with its principal place of business located
22 at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317.

23 54. Defendant, Cornerstone BioPharma, Inc. ("Cornerstone BioPharma"), was at all
24 relevant times a corporation organized under the laws of the State of Nevada, with its principal place
25 of business located at 1255 Crescent Green Drive, Suite 250, Cary, NC 27511.

26 55. Defendant, Cornerstone BioPharma Holdings, Inc., ("Cornerstone Holdings"), was at
27 all relevant times a corporation organized under the laws of the State of Delaware, with its principal
28 place of business located at 1255 Crescent Green Drive, Suite 250, Cary, NC 27511.

1 56. Defendant Qualitest, Defendant Vintage, Defendant Propst, Defendant Brenn
2 Distribution, Defendant, Brenn Manufacturing, Defendant Vintage LLC, Defendant Generics US,
3 Defendant Generics Bidco I, Defendant Generics Bidco II, Defendant Generics US Parent, Defendant
4 Endo, Defendant Endo Holdings, Defendant Cornerstone BioPharma and Defendant, Cornerstone
5 Holdings shall be referred to herein individually by name or jointly as the "Generic Qualitest
6 Defendants."

7 57. At all relevant times, Defendant Generics US Parent owned Defendant Generics Bidco
8 I, Defendant Generics Bidco II and Defendant Generics US.

9 58. Until on or about December 1, 2010, Defendant Qualitest, Defendant Vintage,
10 Defendant Propst, Defendant Brenn Distribution, Defendant, Brenn Manufacturing and/or Defendant
11 Vintage LLC were owned by Defendant Generics US, Defendant Generics Bidco I, Defendant
12 Generics Bidco II and/or Defendant Generics US Parent.

13 59. On or about December 1, 2010, Defendant Endo Holdings acquired Defendant
14 Generics US, Defendant Generics Bidco I, Defendant Generics Bidco II and Defendant Generics US
15 Parent, and presumably indirectly acquired through one or all of them Defendant Qualitest,
16 Defendant Vintage, Defendant Propst, Defendant Brenn Distribution, Defendant, Brenn
17 Manufacturing and/or Defendant Vintage LLC.

18 60. The businesses of Defendant Qualitest, Defendant Vintage, Defendant Propst,
19 Defendant Brenn Distribution, Defendant, Brenn Manufacturing, and/or Defendant Vintage LLC may
20 have been combined thereafter into a single business unit with Defendant Endo.

21 61. Additionally, Cornerstone BioPharma entered into a certain Asset Purchase
22 Agreement and/or Manufacturing Agreement, as amended, with one or more of the other Qualitest
23 Defendants, including but not necessarily limited to Defendant, Vintage, LLC on or about July 20,
24 2004 for the sale, manufacture, marketing, supply, distribution and/or testing of Propoxyphene
25 Products including but not necessarily limited to Propoxyphene Napsylate/APAP 100 in 325mg and
26 500 mg forms.

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1 62. Upon information and belief Defendant Cornerstone Holdings is a parent, subsidiary,
2 affiliate, or other related company through merger or otherwise with Defendant Cornerstone
3 BioPharma.

4 63. The extent to which Defendant Endo and/or Defendant Endo Holdings may have
5 assumed responsibility for the acts, omissions or liability of other Generic Qualitest Defendants,
6 contractually or otherwise, is unknown at this time, and Plaintiffs requires discovery as to this issue.

7 64. It is believed that at all relevant times, Defendant Qualitest, Defendant Vintage,
8 Defendant Propst, Defendant Brenn and/or Defendant Vintage LLC were the holders of approved
9 Abbreviated New Drug Applications ("ANDAs") for prescription pain management medications
10 containing propoxyphene that were generic formulations of Darvocet and/or Darvon.

11 65. It is possible, however, that the ANDA for these generic drugs may have been owned
12 by another of the Generic Qualitest Defendants, or one or more of their subsidiaries, parents or
13 related entities, but Plaintiffs have been unable to determine this, despite diligent and reasonable
14 investigations.

15 66. Despite diligent and reasonable investigations, Plaintiff has been unable to determine
16 the exact relationship between and among the Generic Qualitest Defendants, but believe that each has
17 been in the business of, and been involved with, either directly or indirectly (through each other or
18 other subsidiaries, related entities, third parties, predecessors or successors in interest), developing,
19 designing, researching, testing, licensing, manufacturing, labeling, advertising, promoting, marketing,
20 selling, distributing and introducing into interstate commerce throughout the United States, including
21 in California and San Diego County, generic Propoxyphene Products for use as prescription pain
22 management medications.

23 67. Upon information and belief, the Generic Qualitest Defendants manufactured the
24 majority of the Propoxyphene Products sold at national retailers, including CVS and Wal-Mart, as
25 distributed by McKesson Defendants.

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GENERIC TEVA DEFENDANTS

68. Defendant TEVA Biopharmaceuticals, Inc. ("TEVA Biopharmaceuticals") was at all relevant times a corporation organized under the laws of Delaware, with its principal place of business located at 9410 Key West Avenue, Rockville, Maryland 20850-3345.

69. Defendant TEVA Pharmaceuticals USA, Inc. ("TEVA Pharmaceuticals") was at all relevant times a corporation organized under the laws of Delaware, with its principal place of business located at 1090 Horsham Road, North Wales, Pennsylvania 19454.

70. Defendant TEVA Biopharmaceuticals and Defendant TEVA Pharmaceuticals shall be collectively referred to as the "Generic TEVA Defendants."

71. It is believed that at all relevant times, one or a combination of the Generic TEVA Defendants were holders of approved Abbreviated New Drug Applications ("ANDAs") for prescription pain management medications containing propoxyphene that were generic formulations of Darvocet and/or Darvon.

72. The Generic TEVA Defendants were in the business of and did (either directly or indirectly through subsidiaries, related entities, third parties, predecessors or successors in interest) develop, design, research, test, license, manufacture, label, advertise, promote, market, sell, distribute and introduce into interstate commerce throughout the United States, including in California and San Diego County, generic Propoxyphene Products for use as prescription pain management medications for mild to moderate pain.

GENERIC MYLAN DEFENDANTS

73. Defendant Mylan Pharmaceuticals, Inc. ("Mylan Pharmaceuticals") was at all relevant times a corporation organized under the laws of West Virginia, with its principal place of business located at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

74. Defendant Mylan, Inc. ("Mylan") was at all relevant times a corporation organized under the laws of Pennsylvania, with its principal place of business located at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317, and is the parent corporation of Mylan Pharmaceuticals.

75. Defendant Mylan Pharmaceuticals and Defendant Mylan shall be collectively referred to as the "Generic Mylan Defendants."

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1 distribution and/or marketing of generic Propoxyphene Products shall be referred to herein
2 individually by name or jointly as the "Generic Defendants."

3 **PLAINTIFFS**

4 90. Plaintiffs are individuals who ingested Propoxyphene Products manufactured,
5 marketed, distributed, and sold by Defendants, and suffered severe cardiovascular injuries as a result
6 of said ingestion.

7
8 **FACTUAL BACKGROUND**

9
10 **I. THE DANGERS AND DUBIOUS EFFECTIVENESS OF PROPOXYPHENE PRODUCTS**

11
12 **A. Propoxyphene is a dangerous, ineffective drug.**

13 91. Propoxyphene is a centrally-acting opiate analgesic that is structurally related to
14 methadone.

15 92. Propoxyphene is a pain reliever used to treat mild to moderate pain.

16 93. Propoxyphene is marketed in two chemical forms (propoxyphene hydrochloride and
17 propoxyphene napsylate), and is sold both as a single chemical entity and also in combination with
18 either acetaminophen or aspirin.

19 94. Branded products with the name "Darvocet" contain both propoxyphene and
20 acetaminophen.

21 95. Branded products with the name "Darvon" do not contain acetaminophen.

22 96. In 1971, Eli Lilly conducted seven identically designed efficacy trials for
23 propoxyphene, six of which demonstrated that propoxyphene alone was not significantly superior to
24 placebo. The trials showed, in contrast, that acetaminophen was significantly superior to placebo.

25 97. Propoxyphene also has been plagued by concerns of its potential toxicity for decades.

26 98. for instance, in as early as 1978, the Health Research Group filed a Citizen Petition to
27 the FDA requesting the recall of Darvon, claiming it was a dangerous drug of questionable
28 effectiveness.

1 99. Non-clinical studies conducted in response to the 1978 Citizen Petition supported the
2 hypothesis of certain clinical findings that deaths due to overdoses of propoxyphene could be due to
3 cardiotoxicity from propoxyphene.

4 100. Upon information and belief, Defendants knew of the risks and questionable
5 effectiveness of Propoxyphene Products for decades and failed to convey those concerns to the public
6 and/or properly investigate the concerns.

7 101. According to the FDA, in 2009, approximately ten million people in the United States
8 received prescriptions for Propoxyphene Products.

9 102. However, propoxyphene, when taken as prescribed and intended, causes and
10 contributes to a greatly increased risk of serious and dangerous side effects including, without
11 limitation, heart arrhythmias, myocardial infarctions, other adverse cardiovascular events and/or
12 sudden death.

13 103. These unique and dangerous risks are not present with other practical and medically-
14 feasible alternate pain management medications that do not contain propoxyphene.

15 104. The FDA's adverse event data has confirmed that staggering, serious adverse events
16 have been associated with propoxyphene-containing drugs, including but not limited to heart
17 arrhythmias, atrial fibrillations, tachycardias, bradycardias, myocardial infarctions and/or sudden
18 death.

19 **B. Great Britain and Europe Withdrew Propoxyphene Products.**

20 105. In January 2005, health officials in Great Britain called for a phased withdrawal of
21 propoxyphene-containing products because of concerns about the cardiac effects associated with the
22 use of propoxyphene.

23 106. In the announcement of the phased withdrawal of propoxyphene-containing products
24 in Great Britain, health officials stated that "it has not been possible to identify any patient group in
25 whom the risk benefit (ratio) may be positive."

26 107. British officials further stated that propoxyphene's efficacy "is poorly established and
27 the risk of toxicity in overdose, both accidental and deliberate, is unacceptable" even in "normal
28 therapeutic doses."

1 108. In other words, the British officials found, as Plaintiff herein alleges, that
2 propoxyphene is a dangerous drug even in standard therapeutic doses.

3 109. In addition, a 2009 study titled "Effect of Withdrawal of Co-Proxamol
4 [propoxyphene-acetaminophen] on Prescribing and Deaths from Drug Poisoning in England and
5 Wales: Time Series Analysis" concluded that the phased withdrawal of propoxyphene-containing
6 products in Great Britain resulted in a substantial decline in suicides and accidental deaths involving
7 such products during the phased withdrawal.

8 110. In June 2009, the European Medicines Agency ("EMA") recommended that the
9 marketing authorizations for propoxyphene-containing medications be withdrawn across the
10 European Union because of safety concerns.

11 111. When deciding to ban propoxyphene-containing medications, the EMA stated that
12 "the available evidence suggests that the combination of propoxyphene and acetaminophen (as in
13 Tylenol) is no more effective than acetaminophen on its own."

14 112. The EMA further stated that "the benefits of all medicines containing propoxyphene,
15 either on its own or in combination, do not outweigh their risks."

16
17 **C. The FDA called for the recall of Propoxyphene Products after**
18 **determining that their risks outweighed their benefits.**

19 113. A 2008 report titled "Drugs Identified in Deceased Persons by Florida Medical
20 Examiners" reported that propoxyphene caused eighty deaths in Florida during 2008.

21 114. A 2009 report titled "Drugs Identified in Deceased Persons by Florida Medical
22 Examiners," produced by the Florida Department of Law Enforcement, demonstrated that
23 propoxyphene caused 460 deaths in Florida alone from 2003 through 2007. This death toll equates to
24 4.2 causally-related deaths per 100,000 propoxyphene prescriptions, significantly higher than
25 comparable ratios for alternative drugs examined in the report, such as tramadol, which caused only
26 2.2 deaths per 100,000 prescriptions. A drug was only indicated as the cause of death when, after
27 examining all the evidence and the autopsy and toxicology results, the medical examiner determined
28 the drug played a causal role in the death.

1 115. In 2009, data from the Drug Abuse Warning Network (DAWN) presented to an FDA
2 Advisory Committee demonstrated that in seven of the eight states examined, the number of drug-
3 related deaths per 100,000 prescriptions was higher for propoxyphene than for tramadol or
4 hydrocodone from 2004 through 2007. In the eighth state, propoxyphene resulted in more deaths per
5 100,000 prescriptions than hydrocodone and only slightly less than tramadol.

6 116. Despite overwhelming evidence of the risks of all propoxyphene-containing
7 medications, their withdrawal from European markets, and evidence that Propoxyphene Products
8 were no more effective than Tylenol, Defendants continued to actively market, produce and distribute
9 Propoxyphene Products in the United States, causing injuries that included but were not limited to
10 heart arrhythmias, atrial fibrillations, tachycardias, bradycardias, myocardial infarctions, and/or
11 sudden death.

12 117. In light of these concerns, public interest groups petitioned for an investigation into
13 whether propoxyphene-containing drugs were linked to serious and potentially fatal heart
14 arrhythmias.

15 118. In 2009, in light of these concerns and renewed efforts to recall Propoxyphene
16 Products, the FDA Advisory Committee voted against the continued marketing of propoxyphene-
17 containing products.

18 119. Although the FDA did not follow the Advisory Committee's recall recommendation at
19 that time, it did order Xanodyne to conduct clinical trials to assess the potential for cardiotoxicity
20 associated with propoxyphene use, to prepare a Medication Guide ("MedGuide") as part of a Risk
21 Evaluation and Minimization Strategy ("REMS") to highlight important safeguards for use of the
22 drug, and to issue a Public Health Advisory to underscore safety issues.

23 120. The FDA also ordered Xanodyne to include a "Black Box" warning on its label,
24 effective July 9, 2009, concerning the risk of fatal overdose, the relevant portion of which states as
25 follows:

26 There have been numerous cases of accidental and intentional overdose with
27 propoxyphene products either alone or in combination with other CNS
28 depressants, including alcohol. Fatalities within the first hour of overdosage
are not uncommon. Many of the propoxyphene-related deaths have occurred
in patients with previous histories of emotional disturbances or suicidal

1 ideation/attempts and/or concomitant administration of sedatives,
2 tranquilizers, muscle relaxants, antidepressants, or other CNS-depressant
3 drugs. Do not prescribe propoxyphene for patients who are suicidal or have a
4 history of suicidal ideation.

5 121. The FDA also required Xanodyne to add a Clinical Pharmacology section to its label
6 to include the following warning about dangers associated with propoxyphene:

7 Propoxyphene is a centrally acting opiate analgesic. In vitro studies
8 demonstrated propoxyphene and the metabolite norpropoxyphene inhibit
9 sodium channels (local anesthetic effect) with norpropoxyphene being
10 approximately 2-fold more potent than propoxyphene and propoxyphene
11 approximately 10-fold more potent than lidocaine. Propoxyphene and
12 norpropoxyphene inhibit the voltage-gated potassium current carried by
13 cardiac rapidly activating delayed rectifier (hERG channels) with
14 approximately equal potency. It is unclear if the effects on ion channels occur
15 within therapeutic dose range.

16 122. The FDA also required Xanodyne to add a Special Populations section to its label to
17 include the following warning about the special dangers propoxyphene poses to geriatric patients:

18 After oral administration of propoxyphene in elderly patients (70-78 years),
19 much longer half-lives of propoxyphene and norpropoxyphene have been
20 reported (propoxyphene 13 to 35 h, norpropoxyphene 22 to 41 h). In addition,
21 the AUC was an average of 3-fold higher and the Cmax was an average of
22 2.5-fold higher in the elderly when compared to a younger (20-28 years)
23 population. Longer dosage intervals may be considered in the elderly because
24 the metabolism of propoxyphene may be reduced in this patient population.
25 After multiple oral doses of propoxyphene in elderly patients (70-78 years),
26 the Cmax of the metabolite (norpropoxyphene) was increased 5-fold.

27 123. Similarly, the FDA also required Xanodyne to add the following warning about the
28 special dangers propoxyphene poses to elderly patients to the Precautions section of its label:

Clinical studies of DARVOCET-N did not include sufficient numbers of
subjects aged 65 and over to determine whether they respond differently from
younger subjects. However, postmarketing reports suggest that patients over
the age of 65 may be more susceptible to CNS-related side effects. Therefore,
dose selection for an elderly patient should be cautious, usually starting at the
low end of the dosage range, reflecting the greater frequency of decreased

1 hepatic, renal, or cardiac function, and of concomitant disease or other drug
2 therapy. Decreased total daily dosage should be considered (See DOSAGE
3 and ADMINISTRATION).

4 124. The FDA also required Xanodyne to add the following warnings about
5 propoxyphene's potential for abuse and dependence in a new Drug Abuse and Dependence section of
6 its label:

7 **Controlled Substance**

8 DARVOCET-N is a Schedule IV narcotic under the U.S. Controlled
9 Substances Act. DARVOCET-N can produce drug dependence of the
10 morphine type, and therefore, has the potential for being abused. Psychic
11 dependence, physical dependence and tolerance may develop upon repeated
12 administration. DARVOCET-N should be prescribed and administered with
13 the same degree of caution appropriate to the use of other narcotic-containing
14 medications.

15 **Abuse**

16 Since DARVOCET-N is a mu-opioid agonist, it may be subject to misuse,
17 abuse, and addiction. Addiction to opioids prescribed for pain management
18 has not been estimated. However, requests for opioids from opioid-addicted
19 patients occur. As such, physicians should take appropriate care in
20 prescribing DARVOCET-N.

21 **Dependence**

22 Opioid analgesics may cause psychological and physical dependence.
23 Physical dependence results in withdrawal symptoms in patients who abruptly
24 discontinue the drug after long term administration. Also, symptoms of
25 withdrawal may be precipitated through the administration of drugs with mu-
26 opioid antagonist activity, e.g., naloxone or mixed agonist/antagonist
27 analgesics (pentazocine, butorphanol, nalbuphine, dezocine). (See also
28 OVERDOSAGE section). Physical dependence usually does not occur to a
clinically significant degree, until after several weeks of continued opioid
usage. Tolerance, in which increasingly larger doses are required to produce
the same degree of analgesia, is usually manifested by a shortened duration of
an analgesic effect and subsequently, by decreases in the intensity of
analgesia.

In chronic pain patients, and in opioid-tolerance cancer patients, the
administration of DARVOCET-N should be guided by the degree of tolerance
manifested and the doses needed to adequately relieve pain.

The severity of the DARVOCET-N abstinence syndrome may depend on the degree of physical dependence. Withdrawal is characterized by rhinitis, myalgia, abdominal cramping, and occasional diarrhea. Most observable symptoms disappear in 5 to 14 days without treatment; however, there may be a phase of secondary or chronic abstinence which may last for 2 to 6 months characterized by insomnia, irritability, and muscular aches. The patient may be detoxified by gradual reduction of the dose. Gastrointestinal disturbances or dehydration should be treated with supportive care.

125. Finally, the FDA also required Xanodyne to add the following warnings about tolerance and dependence in the Precautions section of its label:

Tolerance and Physical Dependence

Tolerance is the need for increasing doses of opioids to maintain a defined effect such as analgesia (in the absence of disease progression or other external factors). Physical dependence is manifested by withdrawal symptoms after abrupt discontinuation of a drug or upon administration of an antagonist. Physical dependence and tolerance are not unusual during chronic opioid therapy.

The opioid abstinence or withdrawal syndrome is characterized by some or all of the following: restlessness, lacrimation, rhinorrhea, yawning, perspiration, chills, myalgia, and mydriasis. Other symptoms also may develop, including: irritability, anxiety, backache, joint pain, weakness, abdominal cramps, insomnia, nausea, anorexia, vomiting, diarrhea, or increased blood pressure, respiratory rate, or heart rate. In general, opioids should not be abruptly discontinued (see DOSAGE AND ADMINISTRATION: Cessation of Therapy).

If DARVOCET-N is abruptly discontinued in a physically dependent patient, an abstinence syndrome may occur (See DRUG ABUSE AND DEPENDENCE). If signs and symptoms of withdrawal occur, patients should be treated by reinstitution of opioid therapy followed by gradual tapered dose reduction of DARVOCET-N combined with symptomatic support (see DOSAGE AND ADMINISTRATION: Cessation of Therapy).

126. Upon information and belief, Xanodyne did not comply with the FDA's mandate to prepare the MedGuide or issue the Public Health Advisory.

127. Upon information and belief, Xanodyne also did not timely implement the Black Box warning or revise the labels for Darvocet or Darvon.

128. Upon information and belief, Xanodyne also did not publish the information in the Physicians' Desk Reference ("PDR"), the primary source of drug warning information for physicians.

1 129. Upon information and belief, Xanodyne also did not communicate the information to
2 prescribing physicians in Dear Health Care Professional letters or by other means.

3 130. The FDA mandate likewise effectively required the Generic Defendants to issue the
4 Black Box warning and label changes, but upon information and belief, the Generic Defendants did
5 not timely implement the Black Box warning or revise the labels for their Propoxyphene Products, or
6 publish the information in the PDR, or communicate the information to prescribing physicians in
7 Dear Health Care Professional letters or by other means.

8 131. Xanodyne did, however, follow part of the FDA mandate by starting to conduct a
9 multiple-ascending dose (MAD) study in July 2009, which confirmed that even when taken at
10 recommended doses, propoxyphene can cause significant changes to the electrical activity of the
11 heart that can be seen on an electrocardiogram (ECG), such as prolonged PR intervals, widened QRS
12 complexes, and prolonged QT intervals.

13 132. An ECG is a recording of the electrical activity generated by the heart as it undergoes
14 depolarization and repolarization, which is the process that causes the muscles in the heart to contract
15 rhythmically and pump blood throughout the body.

16 133. The different waves that comprise the ECG, including the PR intervals, QRS
17 complexes, and QT intervals, represent the sequence of depolarization and repolarization of the atria
18 and ventricles. Abnormalities in the ECG indicate abnormalities in the electrical activity of the heart,
19 specifically the depolarization and repolarization process.

20 134. Changes in the electrical activity of the heart can increase the risk for serious
21 abnormal heart rhythms that have been linked to serious adverse effects, including sudden death.

22 135. Propoxyphene's principal metabolite, norpropoxyphene, is a Sodium channel and
23 hERG channel blocker. Blockage of either of these channels can lead to changes in the electrical
24 activity of the heart and other cardiac injuries.

25 136. The FDA concluded that the safety risks of propoxyphene, including the negative
26 effects of propoxyphene on the electrical activity of the heart, outweigh its benefit for pain relief.

27 137. On November 19, 2010, the FDA announced that Xanodyne had agreed to stop
28 marketing its Propoxyphene Products in the United States.

1 138. Also on November 19, 2010, the FDA requested that the generic manufacturers also
2 remove their Propoxyphene Products.

3 139. Also on November 19, 2010, the FDA advised health care professionals to stop
4 prescribing and dispensing Propoxyphene Products, and to ask their patients to stop taking those
5 drugs.

6 140. In its news release on November 19, 2010, the FDA said that the data showed "that
7 even when taken at recommended doses, propoxyphene causes significant changes to the electrical
8 activity of the heart" and that the changes in electrical activity of the heart "can increase the risk for
9 serious abnormal heart rhythms that have been linked to serious adverse events, including sudden
10 death."

11 **II. DEFENDANTS' NEGLIGENT AND WRONGFUL MARKETING,**
12 **DISTRIBUTING AND SALE OF DEFECTIVELY DESIGNED**
13 **PROPOXYPHENE PRODUCTS**

14 141. At all relevant time, Eli Lilly knew or should have known that Propoxyphene Products
15 were defectively designed.

16 142. As discussed above, in 1978, the Health Research Group filed a Citizen Petition with
17 the FDA seeking the recall of Propoxyphene Products.

18 143. Upon information and belief, the FDA rejected the 1978 recall in large part because of
19 Eli Lilly's vocal and ultimately successful campaign, in which it made numerous false statements
20 regarding the safety and efficacy of Propoxyphene Products, even though it knew or should have
21 known that such statements were false.

22 144. Upon information and belief, Eli Lilly also made commitments to the FDA about the
23 manner in which it would market its Propoxyphene Products to address safety concerns, but failed to
24 live up to these commitments.

25 145. For example, a key factor in the FDA's decision to reject changing the regulatory
26 status of Propoxyphene Products was Eli Lilly's commitment to an educational program to sensitize
27 prescribers and patients to the hazards of propoxyphene products.

28 ///

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1 146. Upon information and belief, Eli Lilly not only failed to emphasize the user warnings
2 in the majority of its physician visits, but also converted that "educational program" into a marketing
3 initiative.

4 147. At all relevant times, Xanodyne focused its sales on pain management products,
5 including Darvocet and Darvon, because the area of pain management offers attractive commercial
6 opportunities in significant markets in the United States.

7 148. At all relevant times, Xanodyne affirmatively decided not to take part in full discovery
8 research of its products because it was and is more beneficial for it to advance products more quickly
9 through abbreviated developmental pathways in order to decrease the time and cost of bringing a new
10 drug to market.

11 149. At all relevant times, Xanodyne extensively marketed Darvocet and Darvon as safe
12 and effective treatments for pain to induce their widespread use, and has received significant profits
13 from the sale of those drugs.

14 150. Similar to Eli Lilly's efforts to defeat the 1978 Propoxyphene Products recall request,
15 as discussed above, Xanodyne also acted to defeat petitions to the FDA to recall Propoxyphene
16 Products.

17 151. Upon information and belief, in April, 2006, Xanodyne made false and misleading
18 statements that it knew or should have known were false and misleading concerning the safety and
19 effectiveness of Propoxyphene Products to the FDA in opposition to a 2006 Citizen Petition
20 requesting the recall of Propoxyphene Products.

21 152. Upon information and belief, Xanodyne also failed to disclose information that was
22 inconsistent with allegations made in the Citizen Petition.

23 153. Additionally, upon information and belief, Xanodyne made a presentation at the
24 FDA's Joint Meeting of the Aesthetic and Life Support Drugs Advisory Committee and Drug Risk
25 Management Committee on January 30, 2009 concerning the same 2006 Citizen Petition to recall
26 Propoxyphene Products, in which it made the following false representations, among others, about
27 Propoxyphene Products, even though it knew such statements to be false:

28 a. that "Darvon and its combinations were effective analgesics";

- b. that Propoxyphene Products are "superior to placebo";
- c. that "Propoxyphene products have a long history in the US of safe and effective use as labeled"; and
- d. that "Petitioner [i.e., Public Citizen in its 2006 FDA Citizen Petition to recall Darvocet] presents no credible scientific evidence that propoxyphene drugs present an imminent hazard to public health or that they are unsafe and ineffective when used according to approved labeling."

154. Upon information and belief, it is believed that the Generic Defendants likewise represented that their Propoxyphene Products were safe and effective for pain management in order to induce their widespread use, and have received significant profits from their sales of those drugs.

155. Defendants knew or should have known of the dangers associated with Propoxyphene Products, including but not limited to the risks of serious abnormal heart rhythms that may cause serious adverse events, including death.

156. Additionally, or in the alternative, Defendants should have started to investigate the link between Propoxyphene Products and cardiac effects significantly before the FDA ordered such an investigation.

157. Had Defendants investigated propoxyphene safety on a timely basis, the associated risks would have been confirmed in time to prevent Plaintiffs from being prescribed or filling prescriptions for Propoxyphene Products, from ingesting or continuing to ingest Propoxyphene Products, and from suffering injuries as a result of those ingestions.

158. Independent of this, before Plaintiffs were injured by ingesting Propoxyphene Products, there was a wealth of scientific and medical evidence available to Defendants – but not to Plaintiffs or their prescribing physicians – to correlate the use of those drugs with the increased risk of developing serious adverse cardiovascular effects, potentially resulting in death, which made those drugs unreasonably dangerous to consumers.

159. Despite what Defendants knew or should have known through the sources cited above, they continued to manufacture and market and sell Propoxyphene Products.

160. Upon information and belief, despite what Defendants knew or should have known through the sources cited above, they failed to provide adequate information to the general public or

1 the health care community – including Plaintiffs and their prescribing physicians – about the
2 correlation between the use of Propoxyphene Products and the increased risk of developing
3 serious adverse cardiovascular effects, potentially resulting in death, which made those drugs
4 unreasonably dangerous to consumers due to the following:

- 5 a. Defendants failed to convey the warnings in a method reasonably calculated to
6 notify the public and the health care community of its risks.
- 7 b. Defendants failed to convey the warning in a location or manner reasonably
8 calculated to notify the public and the health care community of its risks.
- 9 c. Defendants failed to convey the warning by use of facts or information that
10 were known about the risks of Propoxyphene Products.
- 11 d. Defendants failed to convey warnings in a manner that was clear, accurate and
12 properly portrayed the intensity of the risks posed by Propoxyphene Products.
- 13 e. Defendants failed to provide “Dear Health Care Professional” letters to the
14 health care community, as authorized by the FDA at 21 CFR 201.100(d)(1), at
15 all and/or in a manner reasonably calculated to convey the risks associated
16 with Propoxyphene Products.
- 17 f. Defendants failed to provide “Dear Health Care Professional” letters after the
18 inclusion of warning label changes approved and/or required by the FDA,
19 including but not necessarily limited to the 2009 label change requiring a
20 “Black Box” warning, as discussed above.
- 21 g. Defendants failed to take reasonable steps to otherwise notify the public and
22 the health care community of the inclusion of warning label changes approved
23 and/or required by the FDA, including but not necessarily limited to the 2009
24 label change requiring a “Black Box” warning, as discussed above.
- 25 h. The Innovator and Brand Defendants failed to recommend to the FDA through
26 the Changes Being Effected (“CBE”) process that branded Propoxyphene
27 Products include a warning identical or similar to the 2009 “Black Box”
28 warning since Defendants knew or should have known of the risks conveyed in
the “Black Box” warning for years prior to its inclusion in the warning label.
- i. Xanodyne failed to properly notify the public and the health care community
about the health risks conveyed in the 2009 “Black Box” warning even though
the FDA specifically instructed them to do so.
- j. Upon information and belief, Xanodyne continued to promote brand-name
Propoxyphene Products as safe and effective even though it knew this was not

1 correct, before and even after, the FDA ordered Xanodyne to include the
2 "Black Box" warning in 2009.

3 k. Upon information and belief, the Generic Defendants failed to update their
4 labels with certain label changes that the FDA approved and/or ordered for use
5 by the Innovator and Brand Defendants, although Plaintiff must conduct
6 discovery to determine the extent of this failure since the Generic Defendants'
7 warning labels are not included in the Physician's Desk Reference.

8 l. Defendants could have and should have requested stronger warnings for
9 Propoxyphene Products, which the FDA could have then ordered to be
10 included in the label without the need to undertake negotiations with the
11 branded manufacturer.

12 161. As stated above, upon information and belief, Defendants failed to adequately convey
13 or warn the public and the health care community as to the risks associated with Propoxyphene
14 Products, though discovery is necessary as to these issues since this information is, in large part, in
15 control of Defendants.

16 162. Upon information and belief, Defendants continued to promote and affirmatively
17 claim that Propoxyphene Products are safe and effective, although they knew or should have known
18 this was not the case.

19 163. At least in part, the extent, dates and methods by which Defendants continued to
20 promote the safety and effectiveness of Propoxyphene Products is not fully known, as this
21 information is in the control of Defendants, and discovery is necessary to obtain this information.

22 164. Had Defendants stopped selling Propoxyphene Products when they knew or should
23 have known about the increased and unreasonably dangerous risks associated with their use,
24 Plaintiffs would not have been prescribed or would not have filled prescriptions for Propoxyphene
25 Products, would not have ingested or would have stopped ingesting them, and would not have
26 suffered injuries resulting from those ingestions.

27 165. Had the general public or the health care community – including Plaintiffs and their
28 prescribing physicians – been adequately advised of the risks associated with the use of
Propoxyphene Products, Plaintiffs would not have been prescribed or would not have filled
prescriptions for Propoxyphene Products, would not have ingested or would have stopped ingesting
them, and would not have suffered injuries resulting from those ingestions.

1 **III. INNOVATOR AND BRAND DEFENDANTS' OWNERSHIP AND**
 2 **TRANSFERS OF THE DARVOCET AND DARVON NDAs**

3 **A. Eli Lilly owned and then transferred the Darvocet and Darvon NDAs.**

4 166. Prior to 2002, Eli Lilly owned all rights to Darvocet and Darvon, including the NDAs
 5 to sell those products. It had held these rights since FDA approval of Darvon (in 1957) and Darvocet
 6 (in 1973).

7 167. On February 18, 2002, Eli Lilly sold the marketing rights to Darvocet and Darvon to
 8 NeoSan, pursuant to an Assignment, Transfer, and Assumption Agreement between the two.

9 168. Eli Lilly generated substantial revenue and other benefits from this sale.

10 169. Upon information and belief, this sale was made possible, at least in part, because of
 11 Eli Lilly's false and misleading statements regarding the safety and effectiveness of Propoxyphene
 12 Products.

13 170. Upon information and belief, the foregoing misleading statements were made to the
 14 FDA, to the public and to the health care community.

15 171. Plaintiff does not yet know the extent and specifics of such statements, as such
 16 information is in the control of Defendants, and Plaintiff must engage in discovery to learn of same.

17 172. In connection with this transaction, NeoSan acquired the following from Eli Lilly:

- 18
- 19 a. all rights, title and interest in Eli Lilly's propoxyphene or propoxyphene-based
 20 pharmaceutical products (including such products wherein propoxyphene is at
 21 least one of the active ingredients) in all forms marketed or marketable in the
 United States under certain propoxyphene-related product NDAs owned by Eli
 Lilly;
 - 22 b. all propoxyphene-related product NDAs owned by Eli Lilly;
 - 23 c. intellectual property related to the transferred propoxyphene-related
 24 pharmaceutical products, including (1) Eli Lilly's copyrights, including
 25 package inserts, (2) any unique appearance, look, shape, size, or color of the
 26 products, and (3) Eli Lilly's trademarks, including those for the names
 Darvocet-N, Darvon-N, and Darvon.
 - 27 d. marketing and promotional materials related to the acquired products;
 - 28 e. all books and records related to the purchased products; and

- f. with regard to the acquired products, a license to use all Eli Lilly's experience and other know-how.

173. However, Eli Lilly specifically retained a combination patent related to dextropropoxyphene, under patent number 4,594,358, and patent application number 60/188,135, filed March 9, 2000.

174. NeoSan, in turn, granted Eli Lilly the following consideration in connection with the transfer of assets:

- a. \$211,400,000, which Eli Lilly amortized over three years;
- b. royalties based on sales of NeoSan's future developed improvements to the Darvon product line or other products containing the active ingredient propoxyphene and any other pharmaceutical products sold under the name Darvon, Darvocet or other Eli Lilly trademarks, excluding the products specifically acquired from Eli Lilly;
- c. all licenses necessary for Eli Lilly to fulfill its obligations under a manufacturing agreement between the parties (described further infra) or necessary for Eli Lilly to sell the acquired products outside of the United States;
- d. the right to audit NeoSan as related to its "performance" and royalty payment obligations; and
- e. for products using the trademarks transferred in connection with the agreement, NeoSan was obligated to provide to Eli Lilly free of charge two then-current production samples of each such product (with then-current packaging) not manufactured by Eli Lilly, and (ii) permit Eli Lilly to inspect the manufacturing process for each such product, so long as the products were manufactured by parties other than Eli Lilly.

175. Eli Lilly and the aaiPharma Entities further agreed to the following joint obligations:

- a. to cooperate in any inspection, investigation, or other inquiry from a government agency related to the acquired products, including the right to be present during any such inspection and to make the others party's employees available during such investigation;
- b. to form an implementation team to oversee the activities contemplated by the agreement;
- c. to prepare all necessary government filings;

- d. to agree to and execute a manufacturing agreement;
- e. to enter into a "Quality Agreement," which Plaintiff has not been able to discover through public sources;
- f. to permit audits to monitor compliance with the agreements;
- g. to enter into an agreement whereby aaiPharma guaranteed NeoSan's performance;
- h. to keep confidential all confidential information;
- i. to indemnify each other for losses caused by the indemnifying party's breaches of the agreement; and
- j. to bind all successors and assigns.

176. The Assignment, Transfer, and Assumption Agreement specifically indicates that nothing therein would forbid Eli Lilly from fulfilling the requirements of a 1994 propoxyphene supply agreement that it had with Mylan and/or Mylan Pharmaceuticals.

177. In connection with the Assignment, Transfer, and Assumption Agreement, NeoSan and Eli Lilly also entered into a Manufacturing Agreement on February 18, 2002, which was set to expire on December 31, 2004, subject to a six month extension at NeoSan's election.

178. Under the Manufacturing Agreement, NeoSan agreed to purchase a set percentage of its Darvocet and Darvon from Eli Lilly, who would manufacture the products, which equaled 60% in the first year of the contract, 50% in the second contract year, and 40% in the third contract year.

179. The Manufacturing Agreement also obligated Eli Lilly to transfer its existing inventory of Darvocet and Darvon products to NeoSan, and provided that the aaiPharma Entities would "not re-label or over-label any such Product inventory without the prior written consent of Lilly, which consent will not be unreasonably withheld."

180. The publicly available Manufacturing Agreement Plaintiff has been able to discover did not include multiple exhibits and related documents to that agreement, including but not limited to a Quality Agreement setting forth certain quality and regulatory responsibilities relating to the manufacture and release for sale of the Product by Eli Lilly to NeoSan, a schedule setting forth the specifications for manufacturing and packaging the product, a schedule setting forth the amount of

1 inventory transferred from Eli Lilly to the aaiPharma Entities and the prices paid for that product, and
2 a Manufacturing Responsibility Document setting forth additional written instructions regarding the
3 manufacture and sale of the products.

4 181. In addition to NeoSan's agreement with Eli Lilly, aaiPharma LLC entered into a
5 Manufacturing and Supply Agreement with DSM Pharmaceuticals, Inc. ("DSM") on January 26,
6 2004, which specified that DSM would exclusively manufacture and supply Darvocet-N 100 for
7 aaiPharma LLC for five years from the first commercial production of the product.

8 182. The agreement also stated that DSM would be responsible for distributing any product
9 that had already been manufactured by aaiPharma LLC or any third party. Upon information and
10 belief, these "third parties" included Eli Lilly and the products in question included at least the
11 Darvocet-N 100 acquired by the aaiPharma Entities from Eli Lilly.

12
13 **B. The aaiPharma Entities Were Investigated for Securities Fraud and Filed**
14 **for Bankruptcy.**

15 183. After NeoSan acquired the marketing rights to Darvocet and Darvon, the aaiPharma
16 Entities reported high sales for those products in their public filings with the Securities and Exchange
17 Commission ("SEC").

18 184. Certain analysts questioned the public numbers, noting that industry data on written
19 prescriptions did not reflect increased demand for either Darvocet or Darvon and suggesting that the
20 aaiPharma Entities had been engaging in "channel stuffing" for both products, i.e. counting shipped-
21 but-unsold drugs as revenue, even though some of them likely would be returned.

22 185. In 2003, the aaiPharma Entities received a letter from the SEC generally addressing
23 the same issue.

24 186. These issues came to a head in 2004, when the aaiPharma Entities announced an
25 internal investigation and disclosed that they had received five subpoenas from a grand jury in
26 Charlotte, North Carolina seeking information about the sales of Darvocet and Darvon.

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1 187. Ultimately, the aaiPharma Entities disclosed that they had overstated their revenue by
2 counting shipped-but-not sold product (specifically including Darvocet and Darvon) as revenue, and
3 in the wake of this revelation, the company filed for Chapter 11 bankruptcy on May 9, 2005.

4 188. As a result of these events, the aaiPharma Entities' former CEO – David M. Hurley –
5 pled guilty to fraud and financial misrepresentation, and settled civil charges with the SEC.

6 **C. Xanodyne acquired the NDAs for Darvocet and Darvon and assumed the**
7 **aaiPharma Entities' obligations to Eli Lilly**

8 189. On July 25, 2005, the aaiPharma Entities (which were then in the process of
9 bankruptcy proceedings) sold their drug business (including the propoxyphene products) to
10 Xanodyne.

11 190. Specific assets sold included the following:

- 12 a. NDAs related to propoxyphene products, including NDA 10-996 (Darvon
13 Compound, Darvon Compound-65 and Darvon with ASA), NDA 10-997
14 (Darvon 65mg capsules), NDA 16-862 (Darvon N (100 mg tablet)), NDA 17-
15 122 (Darvocet N 50 and Darvocet N 100), NDA 17-507 (Darvocet N
Suspension), and NDA 76-429 (Darvocet A500).
- 16 b. drug manufacturing and investigative files related to propoxyphene products;
- 17 c. all of the aaiPharma Entities' existing inventory of propoxyphene products and
18 propoxyphene bulk active ingredient;
- 19 d. certain intellectual property related to propoxyphene products; and
- 20 e. all of the aaiPharma Entities' rights under certain contracts, specifically
21 including the aaiPharma Entities' rights under the 2002 Assignment, Transfer,
22 and Assumption Agreement between NeoSan and Eli Lilly.

23 191. Xanodyne accordingly assumed NeoSan's obligation to pay Eli Lilly royalties for
24 product reformulations, i.e. the royalty obligation created by the 2002 Assignment, Transfer, and
25 Assumption Agreement.

26 192. Xanodyne also assumed all other obligations of NeoSan under the 2002 Assignment,
27 Transfer, and Assumption Agreement.
28

1 193. The bankruptcy Court authorized assignment of NeoSan's obligations under the 2002
2 Assignment, Transfer, and Assumption agreement to Xanodyne in an order dated July 18, 2005.
3 Bnkrpcy. Ct. Del. 05-11341-CSS, Dckt. # 296.

4 194. The purchase and sale agreement between the aaiPharma Entities and Xanodyne
5 explicitly noted that the aaiPharma Entities were in default on payment obligations for raw
6 propoxyphene purchased from Eli Lilly.

7 195. In conjunction with the purchase and sale agreement, Xanodyne entered into a "Master
8 Services Agreement" with AAI DS.

9 196. Under that agreement, Xanodyne agreed that AAI DS would manufacture 100% of
10 Xanodyne's Darvocet-N 50, Darvon, Darvon-N, and Darvon Compound 65.

11 197. This agreement continued until 2009, when the aaiPharma Entities sold their contract
12 manufacturing assets to AAI Services, a newly created company. AAI Services appears to have
13 manufactured propoxyphene products for Xanodyne until those products were removed from the
14 market.

15 198. Darvocet A500, one of the Propoxyphene Products sold to Xanodyne by the
16 aaiPharma Entities, was purchased by the aaiPharma Entities from Athlon Pharmaceuticals Inc.
17 ("Athlon") in July 2003. Under the terms of the agreement, the aaiPharma Entities owe Athlon
18 royalties in an amount equal to 10% of the net sales of Darvocet A500 and any other combination
19 propoxyphene napsylate and acetaminophen products that they may sell in the future through 2023.

20 199. Darvocet A500 was manufactured and supplied by Mikart, Inc. and was to be supplied
21 by Mikart, Inc. until 2013, but in June 2004, the aaiPharma Entities notified Athlon that Athlon had
22 breached a related services agreement, and initiated litigation. Athlon brought counterclaims seeking
23 payment of unpaid monthly payments under the contract and additional litigation with respect to the
24 royalty provisions in the asset purchase agreement. Despite Plaintiff's best efforts, it remains unclear
25 whether these royalty payments are still owed to Athlon by Xanodyne as the aaiPharma Entities'
26 successor-in-interest.

27 200. On February 21, 2007 Xanodyne and DSM entered into an agreement for the
28 manufacture of Darvocet. Upon information and belief, DSM continued to produce Darvocet-N 100

1 for Xanodyne pursuant to its prior agreement with the aaiPharma Entities, and entered into a separate
2 agreement with Xanodyne to continue manufacturing the same. Therefore, DSM had separate
3 contractual agreements with both the aaiPharma Entities and Xanodyne to manufacture Darvocet.

4 **D. Both the aaiPharma Entities and Xanodyne sold Darvocet and Darvon**
5 **labeled by Eli Lilly.**

6
7 201. Because of the aaiPharma Entities' bankruptcy, the Delaware bankruptcy court had to
8 approve the asset sale.

9 202. In connection with that sale, Eli Lilly filed documents indicating the aaiPharma
10 Entities was responsible for paying Medicare/Medicaid reimbursements for all Darvon or Darvocet
11 products sold after the effective date of the 2002 Assignment, Transfer and Assumption Agreement.

12 203. As described above, the aaiPharma Entities acquired Eli Lilly's inventory of Darvon
13 and Darvocet products when the 2002 Assignment, Transfer and Assumption Agreement was
14 executed. Eli Lilly's filings in the bankruptcy court indicate that this was "product manufactured and
15 labeled by Lilly."

16 204. Individual state Medicaid agencies would invoice Eli Lilly for Medicare or Medicaid
17 reimbursements in connection with sale of the acquired inventory, i.e., Eli Lilly would be charged
18 when NeoSan sold Darvocet or Darvon drawn from Eli Lilly's pre-agreement inventory. Eli Lilly
19 would in turn invoice NeoSan/the aaiPharma Entities for these charges.

20 205. As of July 6, 2005, Eli Lilly contended the aaiPharma Entities owed Eli Lilly
21 \$1,093,931.78 in such charges. Eli Lilly indicated it expected further amounts would accrue between
22 January 1, 2005 and the effective date of Xanodyne's assumption of the 2002 Agreement, and that it
23 was likely that additional amounts would accrue even after Xanodyne assumed the contract, although
24 Plaintiff requires discovery to determine the extent and amount of these payments.

25 206. This indicates that the aaiPharma Entities likely sold Eli Lilly-labeled product even
26 after buying the NDA, and that Xanodyne may have sold the same, although Plaintiff will require
27 discovery to determine the extent and amount of such sales.
28

1 207. Statements made by Xanodyne in public filings confirm this. In a Form S-1 filed with
2 the Securities and Exchange Commission on June 8, 2008, Xanodyne noted that:

3
4 The products that we acquired from AAIPharma in July 2005 had been
5 previously acquired by AAIPharma from various other third parties. Before
6 selling these products to us, AAIPharma continued to use the third parties'
7 National Drug Code, or NDC, numbers for the products. Among other
8 purposes, state Medicare and Medicaid programs use NDC numbers to track
9 product utilization. Because AAIPharma used the third parties' NDC
10 numbers, these third parties paid the Medicaid and Medicare rebates directly
11 and billed AAIPharma in arrears. At the time of acquisition and for a period
12 of time following the acquisition, this created an unpredictable rebate history
13 for these products on which to base our Medicaid and Medicare rebate
14 accruals.

15 208. Upon information and belief, these "third parties" included Eli Lilly and the products
16 in question included the Propoxyphene Products acquired by the aaiPharma Entities from Eli Lilly.

17 209. Xanodyne went on to indicate that they were able to pay the referred-to Medicare
18 rebates directly "after transitioning the NDC numbers for the products to Xanodyne NDC numbers."

19 210. Xanodyne's Form S-1 also noted that Xanodyne believed the trademarks on Darvocet
20 and Darvon were "an important factor in marketing those products," and that it relied on "brand
21 reputation and awareness among physicians and patients to generate ongoing market demand for and
22 sale of" Darvocet and Darvon without promotional efforts from Xanodyne.

23 **E. Xanodyne was Obligated to Pay Royalties to Eli Lilly for Its Sales of**
24 **Darvocet.**

25 211. Xanodyne's 2008 Form In S-1 Registration Statement contained the following
26 assertion:

27 As a result of our acquisition of all of AAIPharma's rights to Darvon and
28 Darvocet, including the related trademarks and NDAs that AAIPharma had
originally acquired from Eli Lilly in February 2002, we have agreed to pay Eli
Lilly a royalty based on net sales in the United States above specified sales
thresholds of all forms of Darvon and Darvocet covered by the acquired
NDAs and, with specified exceptions, any new pharmaceutical product
containing the active pharmaceutical ingredient propoxyphene or the name
"Darvon" or "Darvocet." We do not currently expect to pay this royalty prior
to FDA approval and the initiation of commercial sale of XP20B, which we

1 expect to market as a line extension of our Darvocet brand. We do not
2 anticipate this to occur earlier than 2011.

3 212. That same form contained the following statement:

4 We have agreed to pay AAIPharma a royalty through December 2011 based
5 on quarterly net sales of Zipsor, XP20B and any orally administered follow on
6 products. If we decide to develop any pain products containing the active
7 pharmaceutical ingredient propoxyphene or diclofenac, or opioid products in
8 combination with acetaminophen or an NSAID, or if we elect to continue to
9 develop any pain products offered to us by AAIPharma, we are obligated to
10 pay AAIPharma a royalty based on net sales of such pain products for ten
11 years following commercial launch.

12 213. XP20B was a time-release combination propoxyphene and acetaminophen modified
13 release oral tablet being developed by Xanodyne.

14 **F. Xanodyne Relied on Third Parties to Manufacture and Perform**
15 **Other Services Related to Its Product Line of Propoxyphene Products.**

16 214. Xanodyne has stated in its S-1/A filing of January 11, 2008 that it does not own or
17 operate, and has no plans to establish, any manufacturing facilities for its products, which would
18 include Darvocet and other branded propoxyphene products.

19 215. Xanodyne further stated in this filing that it relies, and continues to rely, upon third
20 parties for the supply of the active pharmaceutical ingredients in its products, which would include
21 Darvocet and other branded propoxyphene products.

22 216. Xanodyne further stated in this filing that it has entered into manufacturing
23 agreements with various entities, including but not limited to, the aaiPharma Entities.

24 217. Xanodyne further stated in this filing that it relies on third parties, such as the
25 aaiPharma Entities, to conduct clinical trials of propoxyphene-containing medications.

26 218. As discovery is on-going, Plaintiff is still in the process of discovering the extent of
27 the various relationships by and among Xanodyne and other Defendants in this case, except to the
28 extent set forth elsewhere in this Complaint.

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G. The Innovator and Brand Defendants Were Inter-Related.

219. Even after selling the intellectual property rights associated with propoxyphene-containing drugs such as Darvocet and Darvon, the Innovator and Brand Defendants retained significant rights and control with respect to the manufacturing, labeling, and distribution of the drugs and continued to reap royalties based on net sales of the drugs in the United States, and as a result, they had an ongoing interest in maintaining sales of Propoxyphene Products such as Darvocet and Darvon.

220. In particular, the Assignment, Transfer, and Assumption Agreement between Eli Lilly and NeoSan referenced above, required Eli Lilly to share its experience and other know-how related to Propoxyphene Products such as Darvocet and Darvon with NeoSan.

221. As a result of the foregoing, the Innovator and Brand Defendants are liable to Plaintiff, jointly and severally, due to the foregoing contractual and other relationships by, between and among the Innovator and Brand Name Defendants, at all relevant times, under the legal doctrine(s) of agency, vicarious liability, and/or respondeat superior.

IV. NDC NUMBERS AND PLAINTIFFS' INGESTION OF PROPOXYPHENE PRODUCTS

222. Upon information and belief, as alleged above, Plaintiffs ingested propoxyphene containing prescription drugs manufactured by Defendants.

223. Ingestion of a prescription drug may be demonstrated by various means. One such method is through the use of a National Drug Code ("NDC") identifier.

224. The NDC number may be, but is not always, helpful in identifying the particular medication taken by a particular patient.

225. For instance, 21 CFR 201.2 states that "[t]he National Drug Code (NDC) number is requested but not required to appear on all drug labels and in all drug labeling, including the label of any prescription drug container furnished to a consumer."

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226. At other times, the pharmacy or other entity dispensing the medication may no longer possess the documents that would provide an otherwise valid NDC number, or some pharmacies do not include NDC numbers in their records.

227. In other instances, it can take six months or longer to obtain records, even from established retail pharmacies. Other, unique problems can arise in obtaining such records for a plaintiff who obtained his or her prescription by mail.

228. Additionally, in a preamble to the NDC directory, the FDA states, among other things, that "The NDC Directory contains ONLY information submitted to FDA in SPL electronic listing files by labelers. (A labeler may be either a manufacturer, including a repackager or relabeler, or, for drugs subject to private labeling arrangements, the entity under whose own label or trade name the product will be distributed.)."

229. In sum, the NDC number is not always available, and there are other methods to establish proof of ingestion of a particular Propoxyphene Product.

FIRST CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – DESIGN DEFECT
(Against All Defendants)

230. Plaintiffs incorporate and adopt by reference each paragraph set forth in this Complaint.

231. At all relevant times, the Innovator and Brand Defendants were engaged in the business of researching, designing, manufacturing, testing, studying, labeling, packaging, distributing, selling, supplying, marketing and/or promoting Darvocet/Darvon, brand-name Propoxyphene Products.

232. At all relevant times, the Generic Defendants were engaged in the business of researching, designing, manufacturing, testing, studying, labeling, packaging, distributing, selling, supplying, marketing and/or promoting generic Propoxyphene Products.

233. At all relevant times, all Propoxyphene Products were associated with a greatly increased risk of developing severe adverse cardiovascular effects that could result in death, and that risk outweighed their benefit for pain relief.

1 234. At all relevant times, practical and medically-feasible alternate pain management
2 medications that did not contain propoxyphene or involve an increased risk of serious adverse
3 cardiovascular effects that could result in death were available.

4 235. At all relevant times, the risks associated with Propoxyphene Products, and the ability
5 to avoid them by using other available, practical and medically-feasible pain management
6 medications, were beyond that which would be contemplated by the ordinary physician who
7 prescribed Propoxyphene Products and the ordinary consumer who purchased Propoxyphene
8 Products.

9 236. At all relevant times, Plaintiffs and their prescribing physicians were unaware of the
10 risks associated with Propoxyphene Products, or of the availability of practical and medically-feasible
11 alternate pain management medications.

12 237. For these reasons, at all relevant times, all of Defendants' Propoxyphene Products
13 were in an unreasonably dangerous and defective condition.

14 238. For these reasons, all of Defendants' Propoxyphene Products that Plaintiffs purchased
15 and ingested were in an unreasonably dangerous and defective condition at the time of purchase.

16 239. All of Defendants' Propoxyphene Products that Plaintiffs purchased and ingested was
17 expected to and did reach Plaintiffs without substantial change in the unreasonably dangerous and in
18 a defective condition in which they were when they left the hands of Defendants.

19 240. Plaintiffs took their Propoxyphene Products in the intended and prescribed manner,
20 and as a direct and proximate result, suffered the injuries described above.

21 241. As a direct and proximate result of the defective and inappropriate design and the
22 unreasonably dangerous and defective characteristics of the Propoxyphene Products and the
23 Defendants' failure to comply with federal standards and requirements, the Plaintiffs suffered severe
24 and permanent injuries. Plaintiffs endured substantial conscious pain and suffering, both physical
25 and emotional in nature. Plaintiffs incurred significant expenses for medical care and treatment,
26 suffered lost wages and earnings, and were otherwise physically, emotionally, and economically
27 injured. Plaintiffs suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from
28

1 the Defendants as alleged herein. The injuries and damages alleged herein are permanent and will
2 continue into the future.

3 242. The aforesaid conduct of the Defendants was committed with knowing, conscious, and
4 deliberate disregard for the rights and safety of consumers, including Plaintiffs herein, thereby
5 entitling Plaintiffs to punitive damages in an amount appropriate to punish the Defendants and deter
6 them from similar conduct in the future.

7 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble, and
8 punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the
9 Court deems proper.

10 **SECOND CAUSE OF ACTION**
11 **STRICT PRODUCTS LIABILITY – FAILURE TO WARN**
(Against All Defendants)

12 243. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
13 Complaint.

14 244. At all relevant times, the Innovator and Brand Defendants were engaged in the
15 business of researching, designing, manufacturing, testing, studying, labeling, packaging,
16 distributing, selling, supplying, marketing and/or promoting Darvocet/Darvon, brand-name
17 Propoxyphene Products.

18 245. At all relevant times, the Generic Defendants were engaged in the business of
19 researching, designing, manufacturing, testing, studying, labeling, packaging, distributing, selling,
20 supplying, marketing and/or promoting generic Propoxyphene Products.

21 246. At all relevant times:

- 22 a. propoxyphene had not been adequately tested;
- 23 b. Propoxyphene Products were associated with a greatly increased risk of serious
24 adverse cardiovascular events that could result in death, which outweighed
their benefit for pain relief;
- 25 c. the risks, and the nature, scope, severity and duration of any serious side
26 effects, were greater with Propoxyphene Products than with other practical,
medically feasible and available pain management medications;
- 27 d. Propoxyphene Products were unreasonably dangerous to the health of patients
28 suffering from pain; and

- e. Propoxyphene Products were no more effective for pain management than other available, practical, and medically-feasible alternate pain management medications, such as over-the-counter acetaminophen (brand name Tylenol), which posed less risk.

247. At all relevant times, the risks associated with Propoxyphene Products, and the ability to avoid them by using other available, practical and medically-feasible pain management medications, were beyond that which would be contemplated by the ordinary physician who prescribed Propoxyphene Products and the ordinary consumer who purchased Propoxyphene Products.

248. At all relevant times, Plaintiffs and their prescribing physicians were unaware of the risks associated with Propoxyphene Products, or of the availability of practical and medically-feasible alternate pain management medications.

249. At all relevant times, Defendants failed to adequately warn the general public or the medical community – including Plaintiffs and their treating physicians – about any of the risks outlined above, or about the availability of practical and medically-feasible alternatives.

250. More specifically, Defendants failed to adequately warn the general public or the medical community – including Plaintiffs and their treating physicians – that:

- a. In 1971, six out of seven trials demonstrated that while propoxyphene alone was not significantly superior to placebo in managing pain, acetaminophen alone was;
- b. In 1978, the Health Research Group filed a petition with the FDA requesting the recall of Darvon based on its claim that it was a dangerous drug of questionable effectiveness, and subsequently submitted studies supporting that propoxyphene could be toxic to the cardiovascular system;
- c. In January 2005, health officials in Great Britain called for a phased withdrawal of propoxyphene-containing products because they were concerned about the cardiac effects associated with their use and were unable to identify any patient group in whom the risk benefit ratio may be positive;
- d. In June 2009, the European Medicines Agency recommended withdrawal across the European Union of marketing authorizations for propoxyphene-containing medications because available evidence suggested that acetaminophen alone was as effective as an acetaminophen-propoxyphene combination, and that the benefits of medicines containing propoxyphene, either alone or in combination, did not outweigh their risks.

- 1 e. In 2009, the FDA ordered Xanodyne to include a Black Box warning
2 concerning the risk of fatal overdose, and to add warnings to its label about
3 propoxyphene's dangers overall, for elderly patients, and in terms of its
4 potential for abuse and dependence.
- 5 f. In 2009, the FDA also ordered Xanodyne to conduct clinical studies to assess
6 the potential for cardiotoxicity associated with propoxyphene use, to prepare a
7 MedGuide to highlight important safeguards for use of the drug, and to issue a
8 Public Health Advisory to underscore safety issues.
- 9 g. In July 2009, Xanodyne's study confirmed that propoxyphene can cause
10 significant changes to the heart, even when taken at recommended doses.

11 251. Upon information and belief, the Innovator and Brand Defendants did not comply with
12 the FDA's mandate to prepare the MedGuide or issue the Public Health Advisory.

13 252. Upon information and belief, the Innovator and Brand Defendants also did not timely
14 implement the Black Box warning or revise the labels for Darvocet or Darvon, or publish the
15 information in the PDR, or communicate the information to prescribing physicians in Dear Health
16 Care Professional letters or by other means.

17 253. The FDA mandate likewise effectively required the Generic Defendants to issue the
18 Black Box warning and label changes, but upon information and belief, the Generic Defendants
19 likewise did not timely implement the Black Box warning or revise the labels for their Propoxyphene
20 Products, or publish the information in the PDR, or communicate the information to prescribing
21 physicians in Dear Health Care Professional letters or by other means.

22 254. It would have been technologically feasible, and would not have been cost-prohibitive,
23 for Defendants to include adequate warnings and instructions in their marketing and labeling
24 materials, and in their communications to the general public and the health care community.

25 255. Defendants instead used their resources to downplay the risks associated with
26 propoxyphene and Propoxyphene Products in their instructional materials, labeling for, and
27 communications about Propoxyphene Products, which was especially misleading given their past and
28 continued efforts to promote the safety and effectiveness of the drugs.

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1 256. At all relevant times, all of Defendants' Propoxyphene Products were in an
2 unreasonably dangerous and defective condition, because they were distributed without the warnings
3 outlined above.

4 257. For these reasons, all of Defendants' Propoxyphene Products that Plaintiffs purchased
5 and ingested were in an unreasonably dangerous and defective condition at the time of purchase.

6 258. All of Defendants' Propoxyphene Products that Plaintiffs purchased and ingested were
7 expected to and did reach Plaintiffs without substantial change in the unreasonably dangerous and
8 defective condition in which they were when they left the hands of Defendants.

9 259. Plaintiffs took their Propoxyphene Products in the intended and prescribed manner,
10 and as a direct and proximate result, suffered the injuries described above.

11 260. As a direct and proximate result of the defective and inappropriate warnings and the
12 unreasonably dangerous and defective characteristics of propoxyphene, and the Defendants' failure to
13 comply with federal standards and requirements, Plaintiffs suffered severe and permanent injuries as
14 herein alleged. Plaintiffs endured substantial conscious pain and suffering, both physical and
15 emotional in nature. Plaintiffs incurred significant expenses for medical care and treatment, suffered
16 lost wages and earnings, and were otherwise physically, emotionally, and economically
17 injured. Plaintiffs suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from
18 the Defendants as alleged herein. The injuries and damages alleged herein are permanent and will
19 continue into the future.

20 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble,
21 and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other
22 relief as the Court deems proper.

23 **THIRD CAUSE OF ACTION**
24 **STRICT LIABILITY IN TORT**
 (Against All Defendants)

25 261. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
26 Complaint.

27 262. Defendants used and controlled toxic propoxyphene for use in humans.

28 263. Propoxyphene is highly toxic, inherently dangerous, and ultra-hazardous to humans.

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1 271. Because of Defendants' failure to properly design their Propoxyphene Products, those
2 products were placed on the market and sold to Plaintiffs while they were in an unreasonably
3 dangerous and defective condition.

4 272. Plaintiffs purchased and ingested Defendants' Propoxyphene Products, which were in
5 an unreasonably dangerous and defective condition at the time of purchase, in a reasonably
6 foreseeable manner and substantially as intended by Defendants.

7 273. As a direct and proximate result, Plaintiffs suffered the injuries described above.

8 274. It was foreseeable that persons like Plaintiffs who ingested Defendants' Propoxyphene
9 Products would, as a direct and proximate result, suffer those injuries.

10 275. In light of what they knew or should have known, Defendants should have anticipated
11 that these injuries were a likely result of the actions and failures to act described above.

12 276. Through these actions and inactions, Defendants knowingly risked the lives of
13 unsuspecting consumers in order to continue making a profit, and their conduct thus was extreme and
14 outrageous, and warrants an award of punitive damages.

15 277. As a direct and proximate result of the negligent design and the unreasonably
16 dangerous and defective characteristics of propoxyphene, and the Defendants' failure to comply with
17 federal standards and requirements, Plaintiffs suffered severe and permanent injuries as herein
18 alleged. Plaintiffs endured substantial conscious pain and suffering, both physical and emotional in
19 nature. Plaintiffs incurred significant expenses for medical care and treatment, suffered lost wages
20 and earnings, and were otherwise physically, emotionally, and economically injured. Plaintiffs
21 suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from the Defendants as
22 alleged herein. The injuries and damages alleged herein are permanent and will continue into the
23 future.

24 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble, and
25 punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the
26 Court deems proper.

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FIFTH CAUSE OF ACTION
NEGLIGENCE
(Against All Defendants)

278. Plaintiffs incorporate and adopt by reference each paragraph set forth in this Complaint.

279. At all relevant times, the Innovator and Brand Defendants were engaged in the business of researching, testing, studying, distributing, selling, supplying, marketing and/or promoting Darvocet/Darvon, brand-name Propoxyphene Products.

280. At all relevant times, the Generic Defendants were engaged in the business of researching, testing, studying, distributing, selling, supplying, marketing and/or promoting generic Propoxyphene Products.

281. At all relevant times, Defendants had a duty to:

- a. exercise reasonable care to conduct adequate studies, tests, surveillance and analyses to assess the risks and adverse effects associated with their Propoxyphene Products; and
- b. stop distributing, selling and/or supplying them if they discovered that the drugs were unreasonably dangerous and defective.

282. Defendants breached those duties, because:

- a. they failed to timely conduct adequate studies, tests, surveillance and analysis, which would have confirmed that their Propoxyphene Products were unreasonably dangerous and defective, for the reasons described above, and that other practical, medically-feasible and safer alternatives were available; and
- b. they failed to timely stop distributing, selling and/or supplying their Propoxyphene Products once they discovered or should have discovered that those drugs were unreasonably dangerous and defective, and that other practical and medically-feasible alternatives that were safer were available.

283. If Defendants had not breached those duties, their unreasonably dangerous and defective Propoxyphene Products would not have been on the market for Plaintiffs to purchase and ingest, and Plaintiffs would not have suffered the injuries described above.

1 284. Because of these breaches, however, Defendants' unreasonably dangerous and
2 defective Propoxyphene Products were on the market, and Plaintiffs purchased and ingested them in a
3 reasonably foreseeable manner and substantially as intended by Defendants.

4 285. As a direct and proximate result, Plaintiffs suffered the injuries described above.

5 286. It was foreseeable that persons like Plaintiffs who ingested Defendants' Propoxyphene
6 Products would, as a direct and proximate result, suffer those injuries.

7 287. In light of what they knew or should have known, Defendants should have anticipated
8 that these injuries were a likely result of the actions and failures to act described above.

9 288. Through these actions and inactions, Defendants knowingly risked the lives of
10 unsuspecting consumers in order to continue making a profit, and their conduct thus was extreme and
11 outrageous, and warrants an award of punitive damages.

12 289. As a direct and proximate result of the defective manufacturing and the unreasonably
13 dangerous and defective characteristics of propoxyphene, and the Defendants' failure to comply with
14 federal standards and requirements, Plaintiffs suffered severe and permanent injuries as herein
15 alleged. Plaintiffs endured substantial conscious pain and suffering, both physical and emotional in
16 nature. Plaintiffs incurred significant expenses for medical care and treatment, suffered lost wages
17 and earnings, and were otherwise physically, emotionally, and economically injured. Plaintiffs
18 suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from the Defendants as
19 alleged herein. The injuries and damages alleged herein are permanent and will continue into the
20 future.

21 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble, and
22 punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the
23 Court deems proper.

24 **SIXTH CAUSE OF ACTION**
25 **NEGLIGENT FAILURE TO WARN**
 (Against All Defendants)

26 290. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
27 Complaint.
28

1 291. At all relevant times, the Innovator and Brand Defendants were engaged in the
2 business of researching, designing, manufacturing, testing, studying, labeling, packaging,
3 distributing, selling, supplying, marketing and/or promoting Darvocet/Darvon, brand-name
4 Propoxyphene Products.

5 292. At all relevant times, the Generic Defendants were engaged in the business of
6 researching, designing, manufacturing, testing, studying, labeling, packaging, distributing, selling,
7 supplying, marketing and/or promoting generic Propoxyphene Products.

8 293. The following were the duties of the Innovator and Brand Defendants at all relevant
9 times, and the duties of the Generic Defendants following implementation of the Food and Drug
10 Administration Amendments Act of 2007, and possibly before:

- 11
- 12 a. to assess, manage and communicate the risks, dangers and adverse effects
- 13 associated with Propoxyphene Products to the health care community and the
- 14 general public, including Plaintiffs and their prescribing physicians; and
- 15 b. to distribute their Propoxyphene Products with adequate information about the
- 16 appropriate use of the products and their associated risks provided to the
- 17 general public and the health care community, including Plaintiffs and their
- 18 prescribing physicians.

19 294. Before Plaintiffs were injured by ingesting Defendants' Propoxyphene Products,
20 Defendants knew or should have known that:

- 21 a. propoxyphene had not been adequately tested;
- 22 b. Propoxyphene Products were associated with a greatly increased risk of serious
- 23 adverse cardiovascular events that could result in death, which outweighed
- 24 their benefit for pain relief;
- 25 c. the risks, and the nature, scope, severity and duration of any serious side
- 26 effects, were greater with Propoxyphene Products than with other practical,
- 27 medically feasible and available pain management medications;
- 28 d. Propoxyphene Products were unreasonably dangerous to the health of patients
- suffering from pain; and
- e. Propoxyphene Products were no more effective for pain management than
- other available, practical, and medically-feasible alternate pain management

1 medications, such as over-the-counter acetaminophen (brand name Tylenol),
2 which posed less risk.

3 295. At all relevant times, Defendants knew or should have known that the risks associated
4 with Propoxyphene Products, and the ability to avoid them by using other available, practical and
5 medically-feasible pain management medications, were beyond that which would be contemplated by
6 the ordinary physician who prescribed Propoxyphene Products and the ordinary consumer who
7 purchased Propoxyphene Products.

8 296. More specifically, Defendants knew or should have known that the general public and
9 the health care community – including Plaintiffs and their prescribing physicians – would not have
10 been aware of the information outlined above, absent disclosures from Defendants, because:

- 11
- 12 a. the general public and the health care community did not have access to the
13 same resources, analysis and knowledge as Defendants; and
- 14 b. Defendants manufactured, sold and distributed Propoxyphene Products, and
15 would therefore be assumed to have superior knowledge about them.

16 297. At all relevant times, Plaintiffs and their prescribing physicians were unaware of the
17 risks associated with Propoxyphene Products, or of the availability of practical and medically-feasible
18 alternate pain management medications.

19 298. At all relevant times, Defendants failed to adequately disclose to the general public or
20 the medical community – including Plaintiffs and their treating physicians – about any of the risks
21 outlined above, or about the availability of practical and medically-feasible alternatives.

22 299. More specifically, Defendants failed to adequately disclose to the general public or the
23 medical community – including Plaintiffs and their treating physicians, about the following facts that
24 it knew or should have known:

- 25
- 26 a. In 1971, six out of seven trials demonstrated that while propoxyphene alone
27 was not significantly superior to placebo in managing pain, acetaminophen
28 alone was;

- b. In 1978, the Health Research Group filed a petition with the FDA requesting the recall of Darvon based on its claim that it was a dangerous drug of questionable effectiveness, and subsequently submitted studies supporting that propoxyphene could be toxic to the cardiovascular system;
- c. In January 2005, health officials in Great Britain called for a phased withdrawal of propoxyphene-containing products because they were concerned about the cardiac effects associated with their use and were unable to identify any patient group in whom the risk benefit ratio may be positive;
- d. In June 2009, the European Medicines Agency recommended withdrawal across the European Union of marketing authorizations for propoxyphene-containing medications because available evidence suggested that acetaminophen alone was as effective as an acetaminophen-propoxyphene combination, and that the benefits of medicines containing propoxyphene, either alone or in combination, did not outweigh their risks.
- e. In 2009, the FDA ordered Xanodyne to include a Black Box warning concerning the risk of fatal overdose, and to add warnings to its label about propoxyphene's dangers overall, for elderly patients, and in terms of its potential for abuse and dependence.
- f. In 2009, the FDA also ordered Xanodyne to conduct clinical studies to assess the potential for cardiotoxicity associated with propoxyphene use, to prepare a MedGuide to highlight important safeguards for use of the drug, and to issue a Public Health Advisory to underscore safety issues.
- g. In July 2009, Xanodyne's study confirmed that propoxyphene can cause significant changes to the heart, even when taken at recommended doses.

300. Upon information and belief, the Innovator and Brand Defendants did not comply with the FDA's mandate to prepare the MedGuide or issue the Public Health Advisory. The failure to take these actions resulted in inadequate labeling of all Propoxyphene based pharmaceuticals.

301. Upon information and belief, the Innovator and Brand Defendants also did not timely implement the Black Box warning or revise the labels for Darvocet or Darvon, or publish the information in the PDR, or communicate the information to prescribing physicians in Dear Health Care Professional letters or by other means. The failure to take these actions resulted in inadequate labeling of all Propoxyphene based pharmaceuticals.

302. The FDA mandate likewise effectively required the Generic Defendants to issue the Black Box warning and label changes, but upon information and belief, the Generic Defendants likewise did not timely implement the Black Box warning or revise the labels for their Propoxyphene

1 Products, or publish the information in the PDR, or communicate the information to prescribing
2 physicians in Dear Health Care Professional letters or by other means.

3 303. It would have been technologically feasible, and would not have been cost-prohibitive,
4 for Defendants to include adequate disclosures in their marketing and labeling materials, and in their
5 communications to the general public and the health care community.

6 304. Defendants instead used their resources to downplay the risks associated with
7 propoxyphene and Propoxyphene Products in their instructional materials, labeling for, and
8 communications about Propoxyphene Products, which was especially misleading given their past and
9 continued efforts to promote the safety and effectiveness of the drugs.

10 305. Plaintiffs and their prescribing physicians justifiably relied on the lack of information
11 about the risks associated with Propoxyphene Products and/or about other available, practical and
12 medically-feasible pain management medications, and acted upon it, by Plaintiffs' physicians
13 prescribing Propoxyphene Products, and Plaintiffs purchasing and ingesting Defendants'
14 Propoxyphene Products.

15 306. Had Defendants provided adequate disclosures:

- 16
- 17 a. Plaintiffs physicians would not have prescribed Propoxyphene Products, and
18 would have instead prescribed another pain management medication that
19 neither contained propoxyphene nor involved an increased risk of serious
20 adverse cardiovascular events that could result in death, or recommended that
21 Plaintiffs instead take over-the-counter acetaminophen;
- 22 b. Plaintiffs would not have purchased or ingested Defendants' Propoxyphene
23 Products; and
- 24 c. Plaintiffs would not have suffered the injuries described above.

25 307. In light of what Defendants knew or should have known, they should have anticipated
26 that their failure to disclose the dangers of propoxyphene and Propoxyphene Products, and of the
27 availability of practical and medically-feasible alternate pain management medications that posed less
28 risk, would likely result in physicians prescribing Propoxyphene Products, and consumers purchasing

1 and ingesting their Propoxyphene Products, and, as a direct and proximate result, suffering serious
2 adverse cardiovascular effects that could result in death.

3 308. Plaintiffs prescription for and purchase and ingestion of Defendants' Propoxyphene
4 Products, and the injuries described above that followed, were the direct and proximate result of
5 Defendants' failure to disclose.

6 309. By failing to provide adequate disclosures, Defendants knowingly risked the lives of
7 unsuspecting consumers in order to continue making a profit, and their conduct thus was extreme and
8 outrageous, and warrants an award of punitive damages.

9 310. As a direct and proximate result of the defective and inappropriate warnings and the
10 unreasonably dangerous and defective characteristics of propoxyphene, and the Defendants' failure to
11 comply with federal standards and requirements, Plaintiffs suffered severe and permanent injuries as
12 herein alleged. Plaintiffs endured substantial conscious pain and suffering, both physical and
13 emotional in nature. Plaintiffs incurred significant expenses for medical care and treatment, suffered
14 lost wages and earnings, and were otherwise physically, emotionally, and economically injured.
15 Plaintiffs suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from the
16 Defendants as alleged herein. The injuries and damages alleged herein are permanent and will
17 continue into the future.

18 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble, and
19 punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the
20 Court deems proper.

21 **SEVENTH CAUSE OF ACTION**
22 **FRAUDULENT NONDISCLOSURE**
23 **(Against All Defendants)**

24 311. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
25 Complaint.

26 312. At all relevant times, the Innovator and Brand Defendants were engaged in the
27 business of researching, designing, manufacturing, testing, studying, labeling, packaging,
28 distributing, selling, supplying, marketing and/or promoting Darvocet/Darvon, brand-name
Propoxyphene Products.

1 313. At all relevant times, the Generic Defendants were engaged in the business of
2 researching, designing, manufacturing, testing, studying, labeling, packaging, distributing, selling,
3 supplying, marketing and/or promoting generic Propoxyphene Products.

4 314. The following were the duties of the Innovator and Brand Defendants at all relevant
5 times, and the duties of the Generic Defendants following implementation of the Food and Drug
6 Administration Amendments Act of 2007, and possibly before:

- 7
- 8 a. to assess, manage and communicate the risks, dangers and adverse effects
9 associated with Propoxyphene Products to the health care community and the
10 general public, including Plaintiffs and their prescribing physicians; and
- 11 b. to distribute their Propoxyphene Products with adequate information about the
12 appropriate use of the products and their associated risks provided to the
13 general public and the health care community, including Plaintiffs and their
14 prescribing physicians.

15 315. Before Plaintiffs were injured by ingesting Defendants' Propoxyphene Products,
16 Defendants knew that:

- 17 a. propoxyphene had not been adequately tested;
- 18 b. Propoxyphene Products were associated with a greatly increased risk of serious
19 adverse cardiovascular events that could result in death, which outweighed
20 their benefit for pain relief;
- 21 c. the risks, and the nature, scope, severity and duration of any serious side
22 effects, were greater with Propoxyphene Products than with other practical,
23 medically feasible and available pain management medications;
- 24 d. Propoxyphene Products were unreasonably dangerous to the health of patients
25 suffering from pain; and
- 26 e. Propoxyphene Products were no more effective for pain management than
27 other available, practical, and medically-feasible alternate pain management
28 medications, such as over-the-counter acetaminophen (brand name Tylenol),
which posed less risk.

316. At all relevant times, Defendants knew that the risks associated with Propoxyphene
Products, and the ability to avoid them by using other available, practical and medically-feasible pain

1 management medications, were beyond that which would be contemplated by the ordinary physician
 2 who prescribed Propoxyphene Products and the ordinary consumer who purchased Propoxyphene
 3 Products.

4 317. More specifically, Defendants knew that the general public and the health care
 5 community – including Plaintiffs and their prescribing physicians – would not have been aware of the
 6 information outlined above, absent disclosures from Defendants, because:

- 7 a. the general public and the health care community did not have access to the
- 8 same resources, analysis and knowledge as Defendants; and
- 9 b. Defendants manufactured, sold and distributed Propoxyphene Products, and
- 10 would therefore be assumed to have superior knowledge about them.

11
 12 318. At all relevant times, Plaintiffs and their prescribing physicians were unaware of the
 13 risks associated with Propoxyphene Products, or of the availability of practical and medically-feasible
 14 alternate pain management medications.

15 319. At all relevant times, Defendants failed to adequately disclose to the general public or
 16 the medical community – including Plaintiffs and their treating physicians – about any of the risks
 17 outlined above, or about the availability of practical and medically-feasible alternatives.

18 320. More specifically, Defendants failed to adequately disclose to the general public or the
 19 medical community – including Plaintiffs and their treating physicians, about the following facts that
 20 it knew:

- 21 a. In 1971, six out of seven trials demonstrated that while propoxyphene alone
- 22 was not significantly superior to placebo in managing pain, acetaminophen
- 23 alone was;
- 24 b. In 1978, the Health Research Group filed a petition with the FDA requesting
- 25 the recall of Darvon based on its claim that it was a dangerous drug of
- 26 questionable effectiveness, and subsequently submitted studies supporting that
- 27 propoxyphene could be toxic to the cardiovascular system;
- 28 c. In January 2005, health officials in Great Britain called for a phased
- withdrawal of propoxyphene-containing products because they were concerned
- about the cardiac effects associated with their use and were unable to identify
- any patient group in whom the risk benefit ratio may be positive;

- 1 d. In June 2009, the European Medicines Agency recommended withdrawal
2 across the European Union of marketing authorizations for propoxyphene-
3 containing medications because available evidence suggested that
4 acetaminophen alone was as effective as an acetaminophen-propoxyphene
5 combination, and that the benefits of medicines containing propoxyphene,
6 either alone or in combination, did not outweigh their risks.
- 7 e. In 2009, the FDA ordered Xanodyne to include a Black Box warning
8 concerning the risk of fatal overdose, and to add warnings to its label about
9 propoxyphene's dangers overall, for elderly patients, and in terms of its
10 potential for abuse and dependence.
- 11 f. In 2009, the FDA also ordered Xanodyne to conduct clinical studies to assess
12 the potential for cardiotoxicity associated with propoxyphene use, to prepare a
13 MedGuide to highlight important safeguards for use of the drug, and to issue a
14 Public Health Advisory to underscore safety issues.
- 15 g. In July 2009, Xanodyne's study confirmed that propoxyphene can cause
16 significant changes to the heart, even when taken at recommended doses.

17 321. Upon information and belief, the Innovator and Brand Defendants did not comply with
18 the FDA's mandate to prepare the MedGuide or issue the Public Health Advisory. The failure to take
19 these actions resulted in inadequate labeling of all Propoxyphene based pharmaceuticals.

20 322. Upon information and belief, the Innovator and Brand Defendants also did not timely
21 implement the Black Box warning or revise the labels for Darvocet or Darvon, or publish the
22 information in the PDR, or communicate the information to prescribing physicians in Dear Health
23 Care Professional letters or by other means. The failure to take these actions resulted in inadequate
24 labeling of all Propoxyphene based pharmaceuticals.

25 323. The FDA mandate likewise effectively required the Generic Defendants to issue the
26 Black Box warning and label changes, but upon information and belief, the Generic Defendants
27 likewise did not timely implement the Black Box warning or revise the labels for their Propoxyphene
28 Products, or publish the information in the PDR, or communicate the information to prescribing
physicians in Dear Health Care Professional letters or by other means.

324. It would have been technologically feasible, and would not have been cost-prohibitive,
for the Defendants to include adequate disclosures in their marketing and labeling materials, and in
their communications to the general public and the health care community.

1 325. Defendants instead used their resources to conceal and downplay the risks associated
 2 with Propoxyphene Products in their promotional materials, instructional materials, labeling for, and
 3 communications about Propoxyphene Products, which was especially misleading given their past and
 4 continued efforts to promote the safety and effectiveness of the drugs. Defendants failed to disclose
 5 the material information outlined above because they wanted the general public and the health care
 6 community – including Plaintiffs and their prescribing physicians – to believe that Propoxyphene
 7 Products were safe and effective, and wanted to induce medical providers – including Plaintiffs
 8 prescribing physicians – to prescribe Propoxyphene Products, and consumers – including Plaintiffs –
 9 to purchase and ingest their Propoxyphene Products.

10 326. Plaintiffs and their prescribing physicians justifiably relied on the lack of information
 11 about the risks associated with Propoxyphene Products and/or about other available, practical and
 12 medically-feasible pain management medications, and acted upon it, by Plaintiffs physicians
 13 prescribing Propoxyphene Products, and Plaintiffs purchasing and ingesting Defendants'
 14 Propoxyphene Products.

15 327. Had Defendants provided adequate disclosures:

- 16 a. Plaintiffs physicians would not have prescribed Propoxyphene Products, and
 17 would have instead prescribed another pain management medication that
 18 neither contained propoxyphene nor involved an increased risk of serious
 19 adverse cardiovascular events that could result in death, or recommended that
 Plaintiffs instead take over-the-counter acetaminophen;
- 20 b. Plaintiffs would not have purchased or ingested Defendants' Propoxyphene
 21 Products; and
- 22 c. Plaintiffs would not have suffered the injuries described above.

23 328. In light of what Defendants knew, they had to have known or anticipated that their
 24 failure to disclose the dangers of propoxyphene and Propoxyphene Products, and of the availability of
 25 practical and medically-feasible alternate pain management medications that posed less risk, would
 26 likely result in physicians prescribing Propoxyphene Products, and consumers purchasing and
 27
 28

1 ingesting their Propoxyphene Products, and, as a direct and proximate result, suffering serious
2 adverse cardiovascular effects that could result in death.

3 329. Plaintiffs prescription for and purchase and ingestion of Defendants' Propoxyphene
4 Products, and the injuries described above that followed, were the direct and proximate result of
5 Defendants' knowing failure to disclose.

6 330. By failing to make the disclosures outlined above, Defendants knowingly risked the
7 lives of unsuspecting consumers in order to continue making a profit, and their conduct thus was
8 extreme and outrageous, and warrants an award of punitive damages.

9 331. Upon information and belief, Plaintiffs allege that Defendants actively and
10 fraudulently concealed information in Defendants' exclusive possession regarding the hazards
11 associated with the Propoxyphene Products with the purpose of preventing consumers, such as
12 Plaintiffs, from discovery these hazards.

13 332. As a direct and proximate result of the defective manufacturing and the unreasonably
14 dangerous and defective characteristics of the Propoxyphene Products and the Defendants' failure to
15 comply with federal standards and requirements, the Plaintiffs suffered severe and permanent
16 injuries. Plaintiffs endured substantial conscious pain and suffering, both physical and emotional in
17 nature. Plaintiffs incurred significant expenses for medical care and treatment, suffered lost wages
18 and earnings, and was otherwise physically, emotionally, and economically injured. Plaintiffs
19 suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from the Defendants as
20 alleged herein. The injuries and damages alleged herein are permanent and will continue into the
21 future.

22 333. Defendants acted willfully or with gross negligence indicating a wanton disregard for
23 the rights of Plaintiffs and others, rendering Defendants liable to Plaintiffs for punitive damages. The
24 aforesaid conduct of the Defendants was committed with knowing, conscious, and deliberate
25 disregard for the rights and safety of consumers, including Plaintiffs herein, thereby entitled Plaintiffs
26 to punitive damages in an amount appropriate to punish the Defendants and deter them from similar
27 conduct in the future.

28

334. The aforesaid conduct of the Defendants was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including Plaintiffs herein, thereby entitling Plaintiffs to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

EIGHTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION
(Against All Defendants)

335. Plaintiffs incorporate and adopt by reference each paragraph set forth in this Complaint.

336. At all relevant times, the Innovator and Brand Defendants were engaged in the business of researching, designing, manufacturing, testing, studying, labeling, packaging, distributing, selling, supplying, marketing and/or promoting Darvocet/Darvon, brand-name Propoxyphene Products.

337. At all relevant times, the Generic Defendants were engaged in the business of researching, designing, manufacturing, testing, studying, labeling, packaging, distributing, selling, supplying, marketing and/or promoting generic Propoxyphene Products.

338. The following were the duties of the Innovator and Brand Defendants at all relevant times, and the duties of the Generic Defendants following implementation of the Food and Drug Administration Amendments Act of 2007, and possibly before:

- a. to assess, manage and communicate the risks, dangers and adverse effects associated with Propoxyphene Products to the health care community and the general public, including Plaintiff and their prescribing physicians; and
- b. to distribute their Propoxyphene Products with adequate information about the appropriate use of the products and their associated risks provided to the general public and the health care community, including Plaintiffs and their prescribing physicians.

1 339. Before Plaintiffs were injured by ingesting Defendants' Propoxyphene Products,
2 Defendants knew or should have known that:

- 3
- 4 a. propoxyphene had not been adequately tested;
- 5 b. Propoxyphene Products were associated with a greatly increased risk of
6 serious adverse cardiovascular events that could result in death, which
7 outweighed their benefit for pain relief;
- 8 c. the risks, and the nature, scope, severity and duration of any serious side
9 effects, were greater with Propoxyphene Products than with other practical,
10 medically feasible and available pain management medications;
- 11 d. Propoxyphene Products were unreasonably dangerous to the health of patients
12 suffering from pain; and
- 13 e. Propoxyphene Products were no more effective for pain management than
14 other available, practical, and medically-feasible alternate pain management
15 medications, such as over-the-counter acetaminophen (brand name Tylenol),
16 which posed less risk.

17 340. More specifically, Defendants knew or should have known that:

- 18 a. In 1971, six out of seven trials demonstrated that while propoxyphene alone
19 was not significantly superior to placebo in managing pain, acetaminophen
20 alone was;
- 21 b. In 1978, the Health Research Group filed a petition with the FDA requesting
22 the recall of Darvon based on its claim that it was a dangerous drug of
23 questionable effectiveness, and subsequently submitted studies supporting that
24 propoxyphene could be toxic to the cardiovascular system;
- 25 c. In January 2005, health officials in Great Britain called for a phased
26 withdrawal of propoxyphene-containing products because they were concerned
27 about the cardiac effects associated with their use and were unable to identify
28 any patient group in whom the risk benefit ratio may be positive;
- d. In June 2009, the European Medicines Agency recommended withdrawal
across the European Union of marketing authorizations for propoxyphene-
containing medications because available evidence suggested that
acetaminophen alone was as effective as an acetaminophen-propoxyphene
combination, and that the benefits of medicines containing propoxyphene,
either alone or in combination, did not outweigh their risks.

- e. In 2009, the FDA ordered Xanodyne to include a Black Box warning concerning the risk of fatal overdose, and to add warnings to its label about propoxyphene's dangers overall, for elderly patients, and in terms of its potential for abuse and dependence.
- f. In 2009, the FDA also ordered Xanodyne to conduct clinical studies to assess the potential for cardiotoxicity associated with propoxyphene use, to prepare a MedGuide to highlight important safeguards for use of the drug, and to issue a Public Health Advisory to underscore safety issues.
- g. In July 2009, Xanodyne's study confirmed that propoxyphene can cause significant changes to the heart, even when taken at recommended doses.

341. Despite what the Innovator and Brand Defendants knew or should have known, upon information and belief, they represented to the general public and the health care community in reports, press releases, advertising campaigns, television commercials, print advertisements, billboards, other commercial media, promotional materials, instructional materials and labeling that:

- a. propoxyphene had been adequately tested;
- b. Propoxyphene Products were safe and effective for pain management; and
- c. Propoxyphene Products were more effective for pain management than other pain management medications.

342. Similarly, despite what the Generic Defendants knew or should have known, upon information and belief, they represented to the general public and the health care community in their instructional materials and labeling that:

- a. propoxyphene had been adequately tested;
- b. Propoxyphene Products were safe and effective for pain management; and
- c. Propoxyphene Products were more effective for pain management than other pain management medications.

343. These representations made by Defendants were false at the time that they were made, and Defendants knew or should have known that they were false.

344. Defendants knew or should have known that the general public and the health care community – including Plaintiffs and their prescribing physicians – would not have been aware that

1 their statements about the testing, safety and effectiveness associated with Propoxyphene Products
2 were false, and would have instead justifiably relied on them, because:

- 3 a. the general public and the health care community did not have access to the
4 same resources, analysis and knowledge as Defendants; and
- 5 b. Defendants manufactured, sold and distributed Propoxyphene Products, and
6 would therefore be assumed to have superior knowledge about them.

7 345. At all relevant times, Plaintiffs and their prescribing physicians did not, in fact, know
8 that Defendants' misrepresentations were false.

9 346. Because of what Defendants knew or should have known, as described above, they
10 failed to exercise reasonable care or competence in making these misrepresentations.

11 347. Plaintiffs and their prescribing physicians justifiably relied and acted upon
12 Defendants' misrepresentations, by Plaintiffs physicians prescribing Propoxyphene Products, and
13 Plaintiffs purchasing and ingesting Defendants' Propoxyphene Products.

14 348. Had Defendants not made these misrepresentations:

- 15 a. Plaintiffs physicians would not have prescribed Propoxyphene Products, and
16 would have instead prescribed another pain management medication that
17 neither contained propoxyphene nor involved an increased risk of serious
18 adverse cardiovascular events that could result in death, or recommended that
19 Plaintiffs instead take over-the-counter acetaminophen;
- 20 b. Plaintiffs would not have purchased or ingested Defendants' Propoxyphene
21 Products; and
- 22 c. Plaintiffs would not have suffered the injuries described above.

23 349. In light of what Defendants knew or should have known, they should have anticipated
24 that their misrepresentations would likely result in physicians prescribing Propoxyphene Products,
25 and consumers purchasing and ingesting their Propoxyphene Products, and, as a direct and
26 proximate result, suffering serious adverse cardiovascular effects that could result in death.

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1 355. At all relevant times, the Generic Defendants were engaged in the business of
2 researching, designing, manufacturing, testing, studying, labeling, packaging, distributing, selling,
3 supplying, marketing and/or promoting generic Propoxyphene Products.

4 356. The following were the duties of the Innovator and Brand Defendants at all relevant
5 times, and the duties of the Generic Defendants following implementation of the Food and Drug
6 Administration Amendments Act of 2007, and possibly before:

- 7
- 8 a. to assess, manage and communicate the risks, dangers and adverse effects
9 associated with Propoxyphene Products to the health care community and the
10 general public, including Plaintiffs and their prescribing physicians; and
 - 11 b. to distribute their Propoxyphene Products with adequate information about the
12 appropriate use of the products and their associated risks provided to the
13 general public and the health care community, including Plaintiffs and their
14 prescribing physicians.

15 357. Before Plaintiffs was injured by ingesting Defendants' Propoxyphene Products,
16 Defendants knew that:

- 17
- 18 a. propoxyphene had not been adequately tested;
 - 19 b. Propoxyphene Products were associated with a greatly increased risk of serious
20 adverse cardiovascular events that could result in death, which outweighed
21 their benefit for pain relief;
 - 22 c. the risks; and the nature, scope, severity and duration of any serious side
23 effects, were greater with Propoxyphene Products than with other practical,
24 medically feasible and available pain management medications;
 - 25 d. Propoxyphene Products were unreasonably dangerous to the health of patients
26 suffering from pain; and
 - 27 e. Propoxyphene Products were no more effective for pain management than
28 other available, practical, and medically-feasible alternate pain management
medications, such as over-the-counter acetaminophen (brand name Tylenol),
which posed less risk.

358. More specifically, Defendants knew that:

- a. In 1971, six out of seven trials demonstrated that while propoxyphene alone was not significantly superior to placebo in managing pain, acetaminophen alone was;
- b. In 1978, the Health Research Group filed a petition with the FDA requesting the recall of Darvon based on its claim that it was a dangerous drug of questionable effectiveness, and subsequently submitted studies supporting that propoxyphene could be toxic to the cardiovascular system;
- c. In January 2005, health officials in Great Britain called for a phased withdrawal of propoxyphene-containing products because they were concerned about the cardiac effects associated with their use and were unable to identify any patient group in whom the risk benefit ratio may be positive;
- d. In June 2009, the European Medicines Agency recommended withdrawal across the European Union of marketing authorizations for propoxyphene-containing medications because available evidence suggested that acetaminophen alone was as effective as an acetaminophen-propoxyphene combination, and that the benefits of medicines containing propoxyphene, either alone or in combination, did not outweigh their risks.
- e. In 2009, the FDA ordered Xanodyne to include a Black Box warning concerning the risk of fatal overdose, and to add warnings to its label about propoxyphene's dangers overall, for elderly patients, and in terms of its potential for abuse and dependence.
- f. In 2009, the FDA also ordered Xanodyne to conduct clinical studies to assess the potential for cardiotoxicity associated with propoxyphene use, to prepare a MedGuide to highlight important safeguards for use of the drug, and to issue a Public Health Advisory to underscore safety issues.
- g. In July 2009, Xanodyne's study confirmed that propoxyphene can cause significant changes to the heart, even when taken at recommended doses.

359. Despite what the Innovator and Brand Defendants knew, upon information and belief, they falsely represented to the general public and the health care community in reports, press releases, advertising campaigns, television commercials, print advertisements, billboards, other commercial media, promotional materials, instructional material and labeling that:

- a. propoxyphene had been adequately tested;
- b. Propoxyphene Products were safe and effective for pain management; and

- 1 c. Propoxyphene Products were more effective for pain management than other
2 pain management medications.

3 360. Similarly, despite what the Generic Defendants knew, upon information and belief,
4 they falsely represented to the general public and the health care community in their instructional
5 materials and labeling that:

- 6 a. propoxyphene had been adequately tested;
7
8 b. Propoxyphene Products were safe and effective for pain management; and
9
10 c. Propoxyphene Products were more effective for pain management than other
11 pain management medications.

12 361. These representations were all intentionally false and misleading at the time that they
13 were made, and Defendants knew that they were false and misleading, and willfully, wantonly and
14 recklessly disregarded that they were false.

15 362. Defendants knew that the general public and the health care community – including
16 Plaintiffs and their prescribing physicians – would not have been aware that their statements about
17 the testing, safety and effectiveness associated with Propoxyphene Products were false, and would
18 have instead justifiably relied on them, because:

- 19 a. the general public and the health care community did not have access to the
20 same resources, analysis and knowledge as Defendants; and
21
22 b. Defendants manufactured, sold and distributed Propoxyphene Products, and
23 would therefore be assumed to have superior knowledge about them.

24 363. At all relevant times, Plaintiffs and their prescribing physicians did not, in fact, know
25 that Defendants' misrepresentations were false.

26 364. Defendants made these material misrepresentations because they wanted the general
27 public and the health care community to rely on them, and wanted to induce medical providers –
28 including Plaintiffs prescribing physicians – to prescribe Propoxyphene Products, and consumers –
including Plaintiffs – to purchase and ingest their Propoxyphene Products.

1 365. Plaintiffs and their prescribing physicians justifiably relied and acted upon
2 Defendants' misrepresentations, by Plaintiffs physicians prescribing Propoxyphene Products, and
3 Plaintiffs purchasing and ingesting Defendants' Propoxyphene Products.

4 366. Had Defendants not made these misrepresentations:

- 5
- 6 a. Plaintiffs physicians would not have prescribed Propoxyphene Products, and
7 would have instead prescribed another pain management medication that
8 neither contained propoxyphene nor involved an increased risk of serious
9 adverse cardiovascular events that could result in death, or recommended that
10 Plaintiffs instead take over-the-counter acetaminophen;
- 11 b. Plaintiffs would not have purchased or ingested Defendants' Propoxyphene
12 Products, and
- 13 c. Plaintiffs would not have suffered the injuries described above.

14 367. In light of what Defendants knew, they had to have known that their
15 misrepresentations would likely result in physicians prescribing Propoxyphene Products, and
16 consumers purchasing and ingesting their Propoxyphene Products, and, as a direct and proximate
17 result, suffering serious adverse cardiovascular effects that could result in death.

18 368. Plaintiffs prescription for and purchase and ingestion of Propoxyphene Products, and
19 the injuries described above that followed, were the direct and proximate result of Defendants'
20 knowing misrepresentations.

21 369. By making the misrepresentations described above, Defendants knowingly risked the
22 lives of unsuspecting consumers in order to continue making a profit, and their conduct thus was
23 extreme and outrageous, and warrants an award of punitive damages.

24 370. Upon information and belief, Plaintiffs allege that Defendants actively and
25 fraudulently concealed information in Defendants' exclusive possession regarding the hazards
26 associated with the Propoxyphene Products with the purpose of preventing consumers, such as
27 Plaintiffs, from discovering these hazards.

28 371. As a direct and proximate result of the defective manufacturing and the unreasonably
dangerous and defective characteristics of the Propoxyphene Products and the Defendants' failure to

1 comply with federal standards and requirements, the Plaintiffs suffered severe and permanent
 2 injuries. Plaintiffs endured substantial conscious pain and suffering, both physical and emotional in
 3 nature. Plaintiffs incurred significant expenses for medical care and treatment, suffered lost wages
 4 and earnings, and was otherwise physically, emotionally, and economically injured. Plaintiffs
 5 suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from the Defendants as
 6 alleged herein. The injuries and damages alleged herein are permanent and will continue into the
 7 future.

8 372. Defendants acted willfully or with gross negligence indicating a wanton disregard for
 9 the rights of Plaintiffs and others, rendering Defendants liable to Plaintiffs for punitive damages. The
 10 aforesaid conduct of the Defendants was committed with knowing, conscious, and deliberate
 11 disregard for the rights and safety of consumers, including Plaintiffs herein, thereby entitled Plaintiffs
 12 to punitive damages in an amount appropriate to punish the Defendants and deter them from similar
 13 conduct in the future.

14 373. The aforesaid conduct of the Defendants was committed with knowing, conscious, and
 15 deliberate disregard for the rights and safety of consumers, including Plaintiffs herein, thereby
 16 entitling Plaintiffs to punitive damages in an amount appropriate to punish the Defendants and deter
 17 them from similar conduct in the future.

18 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble, and
 19 punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the
 20 Court deems proper.

21 **TENTH CAUSE OF ACTION**
 22 **NEGLIGENCE PER SE**
(Against All Defendants)

23 374. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
 24 Complaint.

25 375. At all relevant times, the Innovator and Brand Defendants were engaged in the
 26 business of researching, designing, manufacturing, testing, studying, labeling, packaging,
 27 distributing, selling, supplying, marketing and/or promoting Darvocet/Darvon, brand-name
 28 Propoxyphene Products.

1 376. At all relevant times, the Generic Defendants were engaged in the business of
2 researching, designing, manufacturing, testing, studying, labeling, packaging, distributing, selling,
3 supplying, marketing and/or promoting generic Propoxyphene Products.

4 377. Under the doctrine of negligence per se, otherwise known as statutory negligence, the
5 duty of Defendants to exercise reasonable care included the obligation to conform their products and
6 activities related to those products to safety standards imposed by applicable statutes or regulations.

7 378. At all relevant times, Defendants violated federal standards for the sale of prescription
8 drugs set forth in the Federal Food, Drug and Cosmetic Act, at 21 C.F.R. § 310.303, because their
9 Propoxyphene Products were not safe and effective for their intended use.

10 379. Additionally, there were violations of federal standards for the sale of prescription
11 drugs set forth in the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, et seq., by the
12 Innovator and Brand Defendants at all relevant times, and by the Generic Defendants following
13 implementation of the Food and Drug Administration Amendments Act of 2007, and possibly before,
14 as follows:

- 15 a. Their Propoxyphene Products were adulterated pursuant to 21 U.S.C. § 351
16 because, among other things, their quality fell below the standard set forth in
17 the official compendium for their Propoxyphene Products and such deviations
18 were not plainly stated in their labels.
- 19 b. Their Propoxyphene Products were misbranded pursuant to 21 U.S.C. § 352
20 because, among other things, their labeling was false or misleading.
- 21 c. Their Propoxyphene Products were misbranded pursuant to 21 U.S.C. § 352
22 because words, statements or other information required by or under authority
23 of that section were not prominently placed thereon with such conspicuousness
24 and in such terms as to render them likely to be read and understood by the
25 ordinary individual under customary conditions of purchase and use.
- 26 d. Their Propoxyphene Products were misbranded pursuant to 21 U.S.C. § 352
27 because the labeling did not bear adequate directions for use, and/or the
28 labeling did not bear adequate warnings against use where their use may have
been dangerous to health or against unsafe dosage or methods or duration of
administration or application, in such manner and form as were necessary for
the protection of users.
- e. Their Propoxyphene Products were misbranded pursuant to 21 U.S.C. § 352
because they were dangerous to health when used in the dosage or manner, or

1 with the frequency or duration prescribed, recommended, or suggested in the
labeling thereof.

- 2 f. Their Propoxyphene Products' labeling was not informative and accurate as
3 required by 21 C.F.R. § 201.56.
- 4 g. Their Propoxyphene Products were misbranded pursuant to 21 C.F.R. § 201.56
5 because the labeling was not updated as new information became available that
6 caused the labeling to become inaccurate, false or misleading.
- 7 h. Their Propoxyphene Products were mislabeled pursuant to 21 C.F.R. § 201.57
8 because the labeling failed to describe serious adverse reactions and potential
9 safety hazards, limitations in use imposed by them, and steps that should be
10 taken if they occur.
- 11 i. Their Propoxyphene Products were mislabeled pursuant to 21 C.F.R. § 201.57
12 because the labeling was not revised to include a warning as soon as there was
13 reasonable evidence of an association of a serious hazard with the drugs.
- 14 j. Defendants failed to list the adverse reactions that occurred with their
15 Propoxyphene Products and other drugs in the same pharmacologically active
16 and chemically related class, as required by 21 C.F.R. § 201.57.
- 17 k. Defendants violated 21 C.F.R. § 310.303 by failing to establish and maintain
18 records and make reports related to clinical experience or other data or
19 information necessary to make or facilitate a determination of whether there
20 were or might have been grounds for suspending or withdrawing approval of
21 the application for their Propoxyphene Products to the FDA.

22 380. Such violations constitute a breach of duty of reasonable care toward Plaintiffs that
23 would subject Defendants to civil liability for personal injuries proximately caused by the violations.

24 381. As a lawful consumer of Defendants' Propoxyphene Products, Plaintiffs was within
25 the class of persons the statutes and regulations described above was designed to protect, and their
26 injuries were the type of harm they were intended to prevent.

27 382. As a direct and proximate cause of the violations of these statutes and regulations by
28 Defendants, which therefore constitute negligent per se acts and/or omissions, Plaintiffs suffered the
injuries set forth in this Complaint.

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///

1 383. By violating these statutes and regulations, Defendants knowingly risked the lives of
2 unsuspecting consumers in order to continue making a profit, and their conduct thus was extreme and
3 outrageous, and warrants an award of punitive damages.

4 384. As a direct and proximate result of the defective and inappropriate warnings and the
5 unreasonably dangerous and defective characteristics of propoxyphene, and the Defendants' failure to
6 comply with federal standards and requirements, Plaintiffs suffered severe and permanent injuries as
7 herein alleged. Plaintiffs endured substantial conscious pain and suffering, both physical and
8 emotional in nature. Plaintiffs incurred significant expenses for medical care and treatment, suffered
9 lost wages and earnings, and were otherwise physically, emotionally, and economically injured.
10 Plaintiffs suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from the
11 Defendants as alleged herein. The injuries and damages alleged herein are permanent and will
12 continue into the future.

13 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble, and
14 punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the
15 Court deems proper.

16 **ELEVENTH CAUSE OF ACTION**
17 **BREACH OF EXPRESS WARRANTY**
 (Against All Defendants)

18 385. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
19 Complaint.

20 386. At all relevant times, the Innovator and Brand Defendants were engaged in the
21 business of selling goods, which were Darvocet/Darvon.

22 387. At all relevant times, the Generic Defendants were engaged in the business of selling
23 goods, which were generic Propoxyphene Products.

24 388. Upon information and belief, at all relevant times, Defendants expressly warranted
25 that:

- 26 a. propoxyphene, such as that contained in their Propoxyphene Products, had
 been adequately tested;
- 27 b. propoxyphene, such as that contained in their Propoxyphene Products, was
28 safe and effective for pain management; and

- 1 c. Propoxyphene Products, such as their Propoxyphene Products, were more
2 effective for pain management than other pain management medications.

3 389. Upon information and belief, Defendants made these express warranties for the benefit
4 of Plaintiffs.

5 390. These express warranties were relied upon, and were part of the basis of the bargain
6 for, Plaintiffs and their prescribing physicians.

7 391. Defendants' Propoxyphene Products did not conform to these express warranties,
8 because:

- 9 a. Propoxyphene, such as that contained in Defendants' Propoxyphene Products,
10 had not been adequately tested;
- 11 b. Propoxyphene Products, such as Defendants' Propoxyphene Products, were
12 associated with a greatly increased risk of serious adverse cardiovascular
13 events that could result in death, which outweighed their benefit for pain relief;
- 14 c. the risks, and the nature, scope, severity and duration of any serious side
15 effects were greater with Propoxyphene Products, such as Defendants'
16 Propoxyphene Products, than with other practical, medically-feasible and
17 available pain management medications;
- 18 d. Propoxyphene Products, such as Defendants' Propoxyphene Products, were
19 unreasonably dangerous to the health of patients suffering from pain; and
- 20 e. Propoxyphene Products, such as Defendants' Propoxyphene Products, were no
21 more effective for pain management than other practical, medically-feasible
22 and available alternate pain management medications, such as over-the-counter
23 acetaminophen (brand name Tylenol), which posed less risk.

24 392. Had Defendants not made these express warranties:

- 25 a. Plaintiffs physicians would not have prescribed Propoxyphene Products, and
26 would have instead prescribed another pain management medication that
27 neither contained propoxyphene nor involved an increased risk of serious
28 adverse cardiovascular events that could result in death, or recommended that
Plaintiffs instead take over-the-counter acetaminophen;
- b. Plaintiffs would not have purchased or ingested Defendants' Propoxyphene
Products; and
- c. Plaintiffs would not have suffered the injuries described above.

1 393. Upon information and belief, Defendants did, however, make these express
2 warranties, and as a result, Plaintiffs' physicians prescribed Propoxyphene Products, and Plaintiffs
3 purchased and ingested Defendants' Propoxyphene Products, and suffered the injuries described
4 above.

5 394. Plaintiffs' injuries that are described above were the direct and proximate result of
6 Defendants' breach of their express warranties.

7 395. As a direct and proximate result of the defective and inappropriate warnings and the
8 unreasonably dangerous and defective characteristics of propoxyphene, and the Defendants' failure to
9 comply with federal standards and requirements, Plaintiffs suffered severe and permanent injuries as
10 herein alleged. Plaintiffs endured substantial conscious pain and suffering, both physical and
11 emotional in nature. Plaintiffs incurred significant expenses for medical care and treatment, suffered
12 lost wages and earnings, and were otherwise physically, emotionally, and economically injured.
13 Plaintiffs suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from the
14 Defendants as alleged herein. The injuries and damages alleged herein are permanent and will
15 continue into the future.

16 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble, and
17 punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the
18 Court deems proper.

19
20 **TWELFTH CAUSE OF ACTION**
21 **BREACH OF IMPLIED WARRANTY**
22 **(Against All Defendants)**

23 396. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
24 Complaint.

25 397. At all relevant times, the Innovator and Brand Defendants were engaged in the
26 business of selling goods, which were Darvocet/Darvon and owed a duty to consumers regarding all
27 Propoxyphene Products.

28 398. At all relevant times, the Generic Defendants were engaged in the business of selling
goods, which were generic Propoxyphene Products.

1 399. Defendants sold their Propoxyphene Products to Plaintiffs.

2 400. The ordinary purpose for which Propoxyphene Products are used is for safe and
3 effective management of pain.

4 401. The Propoxyphene Products that Defendants sold to Plaintiffs were not fit for their
5 ordinary purpose of providing safe and effective management of pain because:

- 6
- 7 a. Propoxyphene, such as that contained in Defendants' Propoxyphene Products,
had not been adequately tested;
- 8 b. Propoxyphene Products, such as Defendants' Propoxyphene Products, were
9 associated with a greatly increased risk of serious adverse cardiovascular
10 events that could result in death, which outweighed their benefit for pain relief;
- 11 c. the risks, and the nature, scope, severity and duration of any serious side
12 effects were greater with Propoxyphene Products, such as Defendants'
13 Propoxyphene Products, than with other practical, medically-feasible and
available pain management medications;
- 14 d. Propoxyphene Products, such as Defendants' Propoxyphene Products, were
unreasonably dangerous to the health of patients suffering from pain; and
- 15 e. Propoxyphene Products, such as Defendants' Propoxyphene Products, were no
16 more effective for pain management than other practical, medically-feasible
and available alternate pain management medications, such as over-the-counter
17 acetaminophen (brand name Tylenol), which posed less risk.

18 402. Plaintiffs' injuries that are described above were the direct and proximate result of the
19 failure of Defendants' Propoxyphene Products to be fit for their ordinary purpose of providing safe
20 and effective management of pain.

21 403. As a direct and proximate result of the defective and inappropriate warnings and the
22 unreasonably dangerous and defective characteristics of propoxyphene, and the Defendants' failure to
23 comply with federal standards and requirements, Plaintiffs suffered severe and permanent injuries as
24 herein alleged. Plaintiffs endured substantial conscious pain and suffering, both physical and
25 emotional in nature. Plaintiffs incurred significant expenses for medical care and treatment, suffered
26 lost wages and earnings, and were otherwise physically, emotionally, and economically injured.
27 Plaintiffs suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from the
28

1 Defendants as alleged herein. The injuries and damages alleged herein are permanent and will
2 continue into the future.

3 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble, and
4 punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the
5 Court deems proper.

6 **THIRTEENTH CAUSE OF ACTION**
7 **DECEIT BY CONCEALMENT – VIOLATION OF**
8 **CALIFORNIA CIVIL CODE §§ 1709, 1710**
9 **(Against All Defendants)**

10 404. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
11 Complaint.

12 405. The Defendants had actual knowledge based upon studies, published reports, and
13 clinical experience, that products containing propoxyphene created an unreasonable risk of serious
14 bodily injury or should have known such information.

15 406. The Defendants intentionally omitted, concealed and suppressed this information from
16 the product labeling, promoting, and advertising of products containing propoxyphene and instead
17 labeled, promoted, and advertised products containing propoxyphene as safe in order to avoid losses
18 and sustain profits in its sale to consumers, as Defendants knew that Plaintiffs' healthcare providers
19 would not have exposed Plaintiffs to products containing propoxyphene had Plaintiffs' healthcare
20 providers known or otherwise been aware of the true facts concerning propoxyphene administration.

21 407. Plaintiffs and Plaintiffs' healthcare providers reasonably relied, to their detriment,
22 upon the Defendants' fraudulent actions and omissions in their representations concerning the risks of
23 propoxyphene in the labeling, advertising, and promoting of said product.

24 408. Plaintiffs and Plaintiffs' healthcare providers reasonably relied upon the Defendants'
25 representations to them that propoxyphene was safe for human consumption and/or use and that the
26 Defendants' labeling, advertising, and promotions fully described all known risks of propoxyphene.

27 409. The Defendants' actions, concealment and omissions as described herein demonstrate
28 a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

1 410. As a direct and proximate result of the defective and inappropriate warnings and the
 2 unreasonably dangerous and defective characteristics of propoxyphene, and the Defendants' failure to
 3 comply with federal standards and requirements, Plaintiffs suffered severe and permanent injuries as
 4 herein alleged. Plaintiffs endured substantial conscious pain and suffering, both physical and
 5 emotional in nature. Plaintiffs incurred significant expenses for medical care and treatment, suffered
 6 lost wages and earnings, and were otherwise physically, emotionally, and economically injured.
 7 Plaintiffs suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from the
 8 Defendants as alleged herein. The injuries and damages alleged herein are permanent and will
 9 continue into the future.

10 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble, and
 11 punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the
 12 Court deems proper.

13 **FOURTEENTH CAUSE OF ACTION**
 14 **VIOLATION OF BUSINESS AND PROFESSIONS CODE § 17200**
 (Against All Defendants)

15 411. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
 16 Complaint.

17 412. Plaintiffs bring this cause of action pursuant to California Business & Professions
 18 Code § 17204, in Plaintiffs' individual capacities, and not on behalf of the general public.

19 413. California Business & Professions Code § 17200 provides that unfair competition
 20 shall mean and include "all unlawful, unfair or fraudulent business practices and unfair, deceptive,
 21 untrue or misleading advertising."

22 414. The acts and practices described above were and are likely to mislead the general
 23 public and therefore constitute unfair business practices within the meaning of California Business &
 24 Professions Code § 17200. The acts of untrue and misleading advertising are, by definition,
 25 violations of California Business & Professions Code § 17200. This conduct includes, but is not
 26 limited to:

- 27 a. Representing to Plaintiffs, Plaintiffs' physicians, and the general public that
 28 propoxyphene was safe, fit, and effective for human use, knowing that said
 representations were false, and concealing from Plaintiffs, Plaintiffs'

1 physicians, and the general public that propoxyphene had a serious propensity
2 to cause injuries to users;

- 3 b. Engaging in advertising programs designed to create the image, impression and
4 belief by consumers and physicians that propoxyphene was safe for human
5 use, even though the Defendants knew this to be false, and even though the
6 Defendants had no reasonable grounds to believe them to be true; and
- 7 c. Purposely downplaying and understating the health hazards and risks
8 associated with propoxyphene.

9 415. These practices constitute unlawful, unfair and fraudulent business acts or practices,
10 within the meaning of California Business & Professions Code § 17200, as well as unfair, deceptive,
11 untrue and misleading advertising as prohibited by California Business & Professions Code § 17500.

12 416. As a result of their conduct described above, Defendants have been and will be
13 unjustly enriched. Specifically, Defendants have been unjustly enriched by receipt of ill-gotten gains
14 from the sale of propoxyphene in California, sold in large part as a result of the acts and omissions
15 described herein.

16 417. Because of fraudulent misrepresentations made by Defendants as detailed above, and
17 the inherently unfair practice of committing a fraud against the public by intentionally
18 misrepresenting and concealing material information, the acts of Defendants described herein
19 constitute unfair or fraudulent business practices.

20 418. Plaintiffs, pursuant to California Business & Professions Code § 17203, seek an order
21 of this court compelling the Defendants to provide restitution and injunctive relief calling for
22 Defendants, and each of them, to cease unfair business practices in the future.

23 419. As a direct and proximate result of the defective and inappropriate warnings and the
24 unreasonably dangerous and defective characteristics of propoxyphene, and the Defendants' failure to
25 comply with federal standards and requirements, Plaintiffs suffered severe and permanent injuries as
26 herein alleged. Plaintiffs endured substantial conscious pain and suffering, both physical and
27 emotional in nature. Plaintiffs incurred significant expenses for medical care and treatment, suffered
28 lost wages and earnings, and were otherwise physically, emotionally, and economically injured.
Plaintiffs suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from the

1 Defendants as alleged herein. The injuries and damages alleged herein are permanent and will
 2 continue into the future.

3 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble, and
 4 punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the
 5 Court deems proper.

6 **FIFTEENTH CAUSE OF ACTION**
VIOLATION OF BUSINESS AND PROFESSIONS CODE § 17500
 7 **(Against All Defendants)**

8 420. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
 9 Complaint.

10 421. Plaintiffs bring this cause of action pursuant to California Business & Professions
 11 Code § 17500, in Plaintiffs' individual capacities and not on behalf of the general public.

12 422. California Business & Professions Code § 17500 provides that it is unlawful for any
 13 person, firm, corporation or association to dispose of property or perform services, or to induce the
 14 public to enter into any obligation relating thereto, through the use of untrue or misleading
 15 statements.

16 423. At all times herein alleged Defendants have committed acts of disseminating untrue
 17 and misleading statements as defined by California Business & Professions Code § 17500 by
 18 engaging in the following acts and practices with intent to induce members of the public, including
 19 healthcare professionals, to purchase and use products containing propoxyphene:

- 21 a. Representing to Plaintiffs, Plaintiffs' physicians, and the general public that
 22 propoxyphene was safe, fit, and effective for human use, knowing that said
 23 representations were false, and concealing from Plaintiffs, Plaintiffs'
 24 physicians, and the general public that propoxyphene had a serious propensity
 25 to cause injuries to users;
- 26 b. Engaging in advertising programs designed to create the image, impression and
 27 belief by consumers and physicians that propoxyphene was safe for human
 28 use, even though the Defendants knew this to be false, and even though the
 Defendants had no reasonable grounds to believe them to be true; and
- c. Purposely downplaying and understating the health hazards and risks
 associated with propoxyphene.

1 424. The foregoing practices constitute false and misleading advertising within the meaning
2 of California Business & Professions Code § 17500.

3 425. As a result of their conduct described above, Defendants have been and will be
4 unjustly enriched. Specifically, Defendants have been unjustly enriched by receipt of ill-gotten gains
5 from the sale and prescription of products containing propoxyphene in California, sold in large part
6 as a result of the acts and omissions described herein.

7 426. Pursuant to California Business & Professions Code § 17535, Plaintiffs seek an order
8 of this court compelling the Defendants to provide restitution and injunctive relief calling for
9 Defendants, and each of them, to cease unfair business practices in the future.

10 427. Plaintiffs seek restitution of the monies collected by Defendants, and each of them,
11 and other injunctive relief to cease such false and misleading advertising in the future.

12 428. As a direct and proximate result of the defective and inappropriate warnings and the
13 unreasonably dangerous and defective characteristics of propoxyphene, and the Defendants' failure to
14 comply with federal standards and requirements, Plaintiffs suffered severe and permanent injuries as
15 herein alleged. Plaintiffs endured substantial conscious pain and suffering, both physical and
16 emotional in nature. Plaintiffs incurred significant expenses for medical care and treatment, suffered
17 lost wages and earnings, and were otherwise physically, emotionally, and economically injured.
18 Plaintiffs suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from the
19 Defendants as alleged herein. The injuries and damages alleged herein are permanent and will
20 continue into the future.

21 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble, and
22 punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the
23 Court deems proper.

24 **SIXTEENTH CAUSE OF ACTION**
25 **VIOLATION OF CIVIL CODE § 1750 ET. SEQ.**
 (Against All Defendants)

26 429. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
27 Complaint.
28

1 430. Plaintiffs are informed and believe and thereon allege that Defendants, and each of
2 them, by the acts and misconduct alleged herein, violated the Consumers Legal Remedies Act,
3 California Civil Code §§ 1750 et. seq. ("CLRA").

4 431. Plaintiffs hereby seek injunctive relief as appropriate against Defendants, and each of
5 them, for their violations of California Civil Code §§ 1750 et. seq. The CLRA applies to Defendants'
6 actions and conduct described herein because it extends to transactions which are intended to result,
7 or which have resulted, in the sale of goods to consumers.

8 432. Plaintiffs are a "consumer" within the meaning of California Civil Code § 1761(d).

9 433. Defendants have violated, and continue to violate, the CLRA in representing that
10 goods have characteristics and benefits which they do not have in violation of California Civil Code §
11 1770(a)(5).

12 434. At all times herein alleged Defendants have committed acts of disseminating untrue
13 and misleading statements as defined by California Civil Code § 1770 by engaging in the following
14 acts and practices with intent to induce members of the public, including healthcare providers, to
15 purchase and use products containing propoxyphene, but is not limited to:

- 16
17 a. Representing to Plaintiffs, Plaintiffs' physicians, and the general public that
18 propoxyphene was safe, fit, and effective for human use, knowing that said
19 representations were false, and concealing from Plaintiffs, Plaintiffs'
20 physicians, and the general public that propoxyphene had a serious propensity
21 to cause injuries to users;
- 22 b. Engaging in advertising programs designed to create the image, impression and
23 belief by consumers and physicians that propoxyphene was safe for human
24 use, even though the Defendants knew this to be false, and even though the
25 Defendants had no reasonable grounds to believe them to be true; and
- 26 c. Purposely downplaying and understating the health hazards and risks
27 associated with propoxyphene.

28 435. The foregoing practices constitute false and misleading advertising and representations
within the meaning of California Civil Code § 1770.

1 436. Pursuant to California Civil Code § 1780, Plaintiffs seek an order of this court for
2 injunctive relief calling for Defendants, and each of them, to cease such deceptive business practices
3 in the future.

4 437. As a direct and proximate result of the defective and inappropriate warnings and the
5 unreasonably dangerous and defective characteristics of propoxyphene, and the Defendants' failure to
6 comply with federal standards and requirements, Plaintiffs suffered severe and permanent injuries as
7 herein alleged. Plaintiffs endured substantial conscious pain and suffering, both physical and
8 emotional in nature. Plaintiffs incurred significant expenses for medical care and treatment, suffered
9 lost wages and earnings, and were otherwise physically, emotionally, and economically injured.
10 Plaintiffs suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from the
11 Defendants as alleged herein. The injuries and damages alleged herein are permanent and will
12 continue into the future.

13 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble, and
14 punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the
15 Court deems proper.

16 **SEVENTEENTH CAUSE OF ACTION**
17 **NEGLIGENCE**
18 **(Against Innovator and Brand Defendants)**

19 438. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
20 Complaint.

21 439. At all relevant times, the Innovator and Brand Defendants were engaged in the
22 business of researching, testing, studying, distributing, selling, supplying, marketing and/or
23 promoting Darvocet and Darvon, brand-name Propoxyphene Products.

24 440. At all relevant times, the Innovator and Brand Defendants had a duty to:

- 25 a. exercise reasonable care to conduct adequate studies, tests, surveillance and
- 26 analyses to assess the risks and adverse effects associated with their
- 27 Propoxyphene Products; and
- 28 b. stop distributing, selling and/or supplying them if they discovered that the
- drugs were unreasonably dangerous and defective.

1 441. At all relevant times, the Innovator and Brand Defendants knew or should have known
2 that physicians who prescribe drugs to their patients, in making their decisions on what to prescribe,
3 often rely on the statements made about the brand formulations of a drug, and thus that the physicians
4 who prescribed either brand or generic Propoxyphene Products to their patients were relying on the
5 statements that the Innovator and Brand Defendants made about Darvocet and/or Darvon.

6 442. At all relevant times, the Innovator and Brand Defendants knew or should have known
7 that patients who are prescribed a brand formulation of a drug are more likely to purchase the generic
8 than the brand formulation, and thus that patients who were prescribed Darvocet and/or Darvon likely
9 would have instead purchased a generic formulation of Darvocet and/or Darvon.

10 443. Because of this knowledge, the duties of the Innovator and Brand Defendants that are
11 outlined above applied at all relevant times not only to the purchasers of the brand products and their
12 prescribing physicians, but also to the purchasers of generic formulations of those drugs and their
13 prescribing physicians, including Plaintiffs and their prescribing physicians.

14 444. This count applies to the Innovator and Brand Defendants in relation to Plaintiffs'
15 ingestion of generic Propoxyphene Products.

16 445. The Innovator and Brand Defendants breached the duties outlined above, because:

- 17
- 18 a. they failed to timely conduct adequate studies, tests, surveillance and analysis,
19 which would have confirmed that their Propoxyphene Products were
20 unreasonably dangerous and defective, for the reasons described above, and
21 that other practical, medically-feasible and safer alternatives were available;
22 and
23 b. they failed to timely stop distributing, selling and/or supplying their
24 Propoxyphene Products once they discovered or should have discovered that
25 those drugs were unreasonably dangerous and defective, and that other
26 practical and medically-feasible alternatives that were safer were available.

27 446. If the Innovator and Brand Defendants had not breached those duties, and had more
28 timely withdrawn their Propoxyphene Products from the market for reasons of safety and efficacy,
the FDA would have also required the withdrawal of all generic Propoxyphene Products.

1 447. If this had occurred, the Generic Defendants' unreasonably dangerous and defective
2 Propoxyphene Products would not have been on the market for Plaintiffs to purchase and ingest, and
3 Plaintiffs would not have suffered the injuries described above.

4 448. Because of these breaches, however, the Generic Defendants' unreasonably dangerous
5 and defective Propoxyphene Products were on the market, and Plaintiffs purchased and ingested them
6 in a reasonably foreseeable manner and substantially as intended by the Innovator and Brand
7 Defendants.

8 449. As a direct and proximate result, Plaintiffs suffered the injuries described above.

9 450. It was foreseeable that if the Innovator and Brand Defendants did not timely withdraw
10 their brand Propoxyphene Products from the market for reasons of safety and efficacy, that the FDA
11 would allow the generic Propoxyphene Products to also remain on the market, and that persons like
12 Plaintiffs would be prescribed Propoxyphene Products, and would purchase and ingest the Generic
13 Defendants' Propoxyphene Products, and, as a direct and proximate result, suffer the injuries that
14 Plaintiffs suffered.

15 451. Through the actions and inactions described above, the Innovator and Brand
16 Defendants knowingly risked the lives of unsuspecting consumers in order to continue making a
17 profit, and their conduct thus was extreme and outrageous, and warrants an award of punitive
18 damages.

19 452. As a direct and proximate result of the defective manufacturing and the unreasonably
20 dangerous and defective characteristics of propoxyphene, and the Defendants' failure to comply with
21 federal standards and requirements, Plaintiffs suffered severe and permanent injuries as herein
22 alleged. Plaintiffs endured substantial conscious pain and suffering, both physical and emotional in
23 nature. Plaintiffs incurred significant expenses for medical care and treatment, suffered lost wages
24 and earnings, and were otherwise physically, emotionally, and economically injured. Plaintiffs
25 suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from the Defendants as
26 alleged herein. The injuries and damages alleged herein are permanent and will continue into the
27 future.

28

1 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble, and
 2 punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the
 3 Court deems proper.

4 **EIGHTEENTH CAUSE OF ACTION**
 5 **FRAUDULENT NONDISCLOSURE**
 6 **(Against Innovator and Brand Defendants)**

7 453. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
 8 Complaint.

9 454. At all relevant times, the Innovator and Brand Defendants were engaged in the
 10 business of researching, designing, manufacturing, testing, studying, labeling, packaging,
 11 distributing, selling, supplying, marketing and/or promoting Darvocet and/or Darvon, brand-name
 12 Propoxyphene Products.

13 455. At all relevant times, the Innovator and Brand Defendants had a duty to:

- 14 a. assess, manage and communicate the risks, dangers and adverse effects
 15 associated with their Propoxyphene Products to the health care community and
 the general public, including Plaintiffs and their prescribing physicians; and
- 16 b. distribute their Propoxyphene Products with adequate information about the
 17 appropriate use of the products and their associated risks provided to the
 18 general public and the health care community, including Plaintiffs and their
 19 prescribing physicians.

20 456. At all relevant times, the Innovator and Brand Defendants knew that physicians who
 21 prescribe drugs to their patients, in making their decisions on what to prescribe, often rely on the
 22 statements made about the brand formulations of a drug, and thus that the physicians who prescribed
 23 either brand or generic Propoxyphene Products to their patients were relying on the statements that
 24 the Innovator and Brand Defendants made about Darvocet and/or Darvon.

25 457. At all relevant times, the Innovator and Brand Defendants knew that patients who are
 26 prescribed a brand formulation of a drug are more likely to purchase the generic than the brand
 27 formulation, and thus that patients who were prescribed Darvocet and/or Darvon likely would have
 28 instead purchased a generic formulation of Darvocet and/or Darvon.

1 458. Because of this knowledge, the duties of the Innovator and Brand Defendants that are
 2 outlined above applied at all relevant times not only to the purchasers of the brand products and their
 3 prescribing physicians, but also to the purchasers of generic formulations of those drugs and their
 4 prescribing physicians, including Plaintiffs and their prescribing physicians.

5 459. This count applies to the Innovator and Brand Defendants in relation to Plaintiffs'
 6 ingestion of generic Propoxyphene Products.

7 460. Before Plaintiffs was injured by ingesting the Generic Defendants' Propoxyphene
 8 Products, the Innovator and Brand Defendants knew that:

- 9
- 10 a. propoxyphene had not been adequately tested;
- 11 b. Propoxyphene Products were associated with a greatly increased risk of serious
 12 adverse cardiovascular events that could result in death, which outweighed
 13 their benefit for pain relief;
- 14 c. the risks, and the nature, scope, severity and duration of any serious side
 15 effects, were greater with Propoxyphene Products than with other practical,
 16 medically feasible and available pain management medications;
- 17 d. Propoxyphene Products were unreasonably dangerous to the health of patients
 18 suffering from pain; and
- 19 e. Propoxyphene Products were no more effective for pain management than
 20 other available, practical, and medically-feasible alternate pain management
 21 medications, such as over-the-counter acetaminophen (brand name Tylenol),
 22 which posed less risk.

23 461. At all relevant times, the Innovator and Brand Defendants knew that the risks
 24 associated with Propoxyphene Products, and the ability to avoid them by using other available,
 25 practical and medically-feasible pain management medications, were beyond that which would be
 26 contemplated by the ordinary physician who prescribed Propoxyphene Products and the ordinary
 27 consumer who purchased Propoxyphene Products.

28 462. More specifically, the Innovator and Brand Defendants knew that the general public
 and the health care community – including Plaintiffs and their prescribing physicians – would not

1 have been aware of the information outlined above, absent disclosures from the Innovator and Brand
2 Defendants, because:

- 3
- 4 a. the general public and the health care community did not have access to the
5 same resources, analysis and knowledge as the Innovator and Brand
6 Defendants; and
- 7 b. the Innovator and Brand Defendants manufactured, sold and distributed
8 Propoxyphene Products, and would therefore be assumed to have superior
9 knowledge about them.

10 463. At all relevant times, Plaintiffs and their prescribing physicians were unaware of the
11 risks associated with Propoxyphene Products, or of the availability of practical and medically-feasible
12 alternate pain management medications.

13 464. At all relevant times, the Innovator and Brand Defendants failed to adequately disclose
14 to the general public or the medical community – including Plaintiffs and their treating physicians –
15 about any of the risks outlined above, or about the availability of practical and medically-feasible
16 alternatives.

17 465. More specifically, the Innovator and Brand Defendants failed to adequately disclose to
18 the general public or the medical community – including Plaintiffs and their treating physicians,
19 about the following facts that it knew:

- 20 a. In 1971, six out of seven trials demonstrated that while propoxyphene alone
21 was not significantly superior to placebo in managing pain, acetaminophen
22 alone was;
- 23 b. In 1978, the Health Research Group filed a petition with the FDA requesting
24 the recall of Darvon based on its claim that it was a dangerous drug of
25 questionable effectiveness, and subsequently submitted studies supporting that
26 propoxyphene could be toxic to the cardiovascular system;
- 27 c. In January 2005, health officials in Great Britain called for a phased
28 withdrawal of propoxyphene-containing products because they were concerned
about the cardiac effects associated with their use and were unable to identify
any patient group in whom the risk benefit ratio may be positive;
- d. In June 2009, the European Medicines Agency recommended withdrawal
across the European Union of marketing authorizations for propoxyphene-

1 containing medications because available evidence suggested that
2 acetaminophen alone was as effective as an acetaminophen-propoxyphene
3 combination, and that the benefits of medicines containing propoxyphene,
4 either alone or in combination, did not outweigh their risks.

5 e. In 2009, the FDA ordered Xanodyne to include a Black Box warning
6 concerning the risk of fatal overdose, and to add warnings to its label about
7 propoxyphene's dangers overall, for elderly patients, and in terms of its
8 potential for abuse and dependence.

9 f. In 2009, the FDA also ordered Xanodyne to conduct clinical studies to assess
10 the potential for cardiotoxicity associated with propoxyphene use, to prepare a
11 MedGuide to highlight important safeguards for use of the drug, and to issue a
12 Public Health Advisory to underscore safety issues.

13 g. In July 2009, Xanodyne's study confirmed that propoxyphene can cause
14 significant changes to the heart, even when taken at recommended doses.

15 466. Upon information and belief, the Innovator and Brand Defendants did not comply with
16 the FDA's mandate to prepare the MedGuide or issue the Public Health Advisory. The failure to take
17 these actions resulted in inadequate labeling of all Propoxyphene based pharmaceuticals.

18 467. Upon information and belief, the Innovator and Brand Defendants also did not timely
19 implement the Black Box warning or revise the labels for Darvocet or Darvon, or publish the
20 information in the PDR, or communicate the information to prescribing physicians in Dear Health
21 Care Professional letters or by other means. The failure to take these actions resulted in inadequate
22 labeling of all Propoxyphene based pharmaceuticals.

23 468. It would have been technologically feasible, and would not have been cost-prohibitive,
24 for the Innovator and Brand Defendants to include adequate disclosures in their marketing and
25 labeling materials, and in their communications to the general public and the health care community.

26 469. The Innovator and Brand Defendants instead used their resources to conceal and
27 downplay the risks associated with Propoxyphene Products in their promotional materials,
28 instructional materials, labeling for, and communications about Propoxyphene Products, which was
especially misleading given their past and continued efforts to promote the safety and effectiveness of
the drugs.

470. The Innovator and Brand Defendants failed to disclose the material information
outlined above because they wanted the general public and the health care community – including

1 Plaintiffs and their prescribing physicians – to believe that Propoxyphene Products were safe and
 2 effective, and wanted to induce medical providers – including Plaintiffs’ prescribing physicians – to
 3 prescribe Propoxyphene Products, and consumers – including Plaintiffs – to request or not resist
 4 those prescriptions.

5 471. Plaintiffs and their prescribing physicians justifiably relied on the lack of information
 6 about the risks associated with Propoxyphene Products and/or about other available, practical and
 7 medically-feasible pain management medications, and acted upon it, by Plaintiffs’ physicians
 8 prescribing Propoxyphene Products, and Plaintiffs requesting or not resisting those prescriptions.

9 472. Had the Innovator and Brand Defendants provided adequate disclosures:

- 10 a. Plaintiffs’ physicians would not have prescribed Propoxyphene Products, and
 11 would have instead prescribed another pain management medication that
 12 neither contained propoxyphene nor involved an increased risk of serious
 13 adverse cardiovascular events that could result in death, or recommended that
 14 Plaintiffs instead take over-the-counter acetaminophen;
- 15 b. Plaintiffs would not have purchased or ingested the Generic Defendants’
 16 Propoxyphene Products; and
- 17 c. Plaintiffs would not have suffered the injuries described above.

18 473. In light of what the Innovator and Brand Defendants knew, they had to have known or
 19 anticipated that their failure to adequately disclose the dangers of propoxyphene and Propoxyphene
 20 Products, and the availability of practical and medically-feasible alternate pain management
 21 medications that posed less risk, would likely result in physicians prescribing Propoxyphene
 22 Products, and consumers purchasing and ingesting generic Propoxyphene Products, and, as a direct
 23 and proximate result, suffering serious adverse cardiovascular effects that could result in death.

24 474. Plaintiffs’ prescription for and purchase and ingestion of the Generic Defendants’
 25 Propoxyphene Products, and the injuries described above that followed, were the direct and
 26 proximate result of the Innovator and Brand Defendants’ knowing failure to disclose.

27 475. By failing to make the disclosures outlined above, the Innovator and Brand
 28 Defendants knowingly risked the lives of unsuspecting consumers in order to continue making a

1 profit, and their conduct thus was extreme and outrageous, and warrants an award of punitive
2 damages.

3 476. Upon information and belief, Plaintiffs allege that Defendants actively and
4 fraudulently concealed information in Defendants' exclusive possession regarding the hazards
5 associated with the Propoxyphene Products with the purpose of preventing consumers, such as
6 Plaintiffs, from discovery these hazards.

7 477. As a direct and proximate result of the defective manufacturing and the unreasonably
8 dangerous and defective characteristics of the Propoxyphene Products and the Defendants' failure to
9 comply with federal standards and requirements, the Plaintiffs suffered severe and permanent
10 injuries. Plaintiffs endured substantial conscious pain and suffering, both physical and emotional in
11 nature. Plaintiffs incurred significant expenses for medical care and treatment, suffered lost wages
12 and earnings, and was otherwise physically, emotionally, and economically injured. Plaintiffs
13 suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from the Defendants as
14 alleged herein. The injuries and damages alleged herein are permanent and will continue into the
15 future.

16 478. Defendants acted willfully or with gross negligence indicating a wanton disregard for
17 the rights of Plaintiffs and others, rendering Defendants liable to Plaintiffs for punitive damages. The
18 aforesaid conduct of the Defendants was committed with knowing, conscious, and deliberate
19 disregard for the rights and safety of consumers, including Plaintiffs herein, thereby entitled Plaintiffs
20 to punitive damages in an amount appropriate to punish the Defendants and deter them from similar
21 conduct in the future.

22 479. The aforesaid conduct of the Defendants was committed with knowing, conscious, and
23 deliberate disregard for the rights and safety of consumers, including Plaintiffs herein, thereby
24 entitling Plaintiffs to punitive damages in an amount appropriate to punish the Defendants and deter
25 them from similar conduct in the future.

26 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble, and
27 punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the
28 Court deems proper.

NINETEENTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION
(Against Innovator and Brand Defendants)

480. Plaintiffs incorporate and adopt by reference each paragraph set forth in this Complaint.

481. At all relevant times, the Innovator and Brand Defendants were engaged in the business of researching, designing, manufacturing, testing, studying, labeling, packaging, distributing, selling, supplying, marketing and/or promoting Darvocet and Darvon, brand-name Propoxyphene Products.

482. At all relevant times, the Innovator and Brand Defendants had a duty to:

- a. assess, manage and communicate the risks, dangers and adverse effects associated with their Propoxyphene Products to the health care community and the general public, including Plaintiffs and their prescribing physicians; and
- b. distribute their Propoxyphene Products with adequate information about the appropriate use of the products and their associated risks provided to the general public and the health care community, including Plaintiffs and their prescribing physicians.

483. At all relevant times, the Innovator and Brand Defendants knew or should have known that physicians who prescribe drugs to their patients, in making their decisions on what to prescribe, often rely on the statements made about the brand formulations of a drug, and thus that the physicians who prescribed either brand or generic Propoxyphene Products to their patients were relying on the statements that the Innovator and Brand Defendants made about Darvocet and/or Darvon.

484. At all relevant times, the Innovator and Brand Defendants knew or should have known that patients who are prescribed a brand formulation of a drug are more likely to purchase the generic than the brand formulation, and thus that patients who were prescribed Darvocet and/or Darvon likely would have instead purchased a generic formulation of Darvocet and/or Darvon.

485. Because of this knowledge, the duties of the Innovator and Brand Defendants that are outlined above applied at all relevant times not only to the purchasers of the brand products and their

1 prescribing physicians, but also to the purchasers of generic formulations of those drugs and their
 2 prescribing physicians, including Plaintiffs and their prescribing physicians.

3 486. This count applies to the Innovator and Brand Defendants in relation to Plaintiffs'
 4 ingestion of generic Propoxyphene Products.

5 487. Before Plaintiffs were injured by ingesting the Generic Defendants' Propoxyphene
 6 Products, the Innovator and Brand Defendants knew or should have known that:

- 7 a. propoxyphene had not been adequately tested;
- 8 b. Propoxyphene Products were associated with a greatly increased risk of serious
 9 adverse cardiovascular events that could result in death, which outweighed
 10 their benefit for pain relief;
- 11 c. the risks, and the nature, scope, severity and duration of any serious side
 12 effects, were greater with Propoxyphene Products than with other practical,
 13 medically feasible and available pain management medications;
- 14 d. Propoxyphene Products were unreasonably dangerous to the health of patients
 15 suffering from pain; and
- 16 e. Propoxyphene Products were no more effective for pain management than
 17 other available, practical, and medically-feasible alternate pain management
 18 medications, such as over-the-counter acetaminophen (brand name Tylenol),
 19 which posed less risk.

20 488. More specifically, the Innovator and Brand Defendants knew or should have known
 21 that:

- 22 a. In 1971, six out of seven trials demonstrated that while propoxyphene alone
 23 was not significantly superior to placebo in managing pain, acetaminophen
 24 alone was;
- 25 b. In 1978, the Health Research Group filed a petition with the FDA requesting
 26 the recall of Darvon based on its claim that it was a dangerous drug of
 27 questionable effectiveness, and subsequently submitted studies supporting that
 28 propoxyphene could be toxic to the cardiovascular system;
- 29 c. In January 2005, health officials in Great Britain called for a phased
 withdrawal of propoxyphene-containing products because they were concerned
 about the cardiac effects associated with their use and were unable to identify
 any patient group in whom the risk benefit ratio may be positive;
- 30 d. In June 2009, the European Medicines Agency recommended withdrawal
 across the European Union of marketing authorizations for propoxyphene-

1 containing medications because available evidence suggested that
 2 acetaminophen alone was as effective as an acetaminophen-propoxyphene
 3 combination, and that the benefits of medicines containing propoxyphene,
 4 either alone or in combination, did not outweigh their risks.

5 e. In 2009, the FDA ordered Xanodyne to include a Black Box warning
 6 concerning the risk of fatal overdose, and to add warnings to its label about
 7 propoxyphene's dangers overall, for elderly patients, and in terms of its
 8 potential for abuse and dependence.

9 f. In 2009, the FDA also ordered Xanodyne to conduct clinical studies to assess
 10 the potential for cardiotoxicity associated with propoxyphene use, to prepare a
 11 MedGuide to highlight important safeguards for use of the drug, and to issue a
 12 Public Health Advisory to underscore safety issues.

13 g. In July 2009, Xanodyne's study confirmed that propoxyphene can cause
 14 significant changes to the heart, even when taken at recommended doses.

15 489. Despite what the Innovator and Brand Defendants knew or should have known, upon
 16 information and belief, the Innovator and Brand Defendants represented to the general public and the
 17 health care community in reports, press releases, advertising campaigns, television commercials, print
 18 advertisements, billboards, other commercial media, promotional materials, instructional material and
 19 labeling that:

- 20 a. propoxyphene had been adequately tested;
- 21 b. Propoxyphene Products were safe and effective for pain management; and
- 22 c. Propoxyphene Products were more effective for pain management than other
 23 pain management medications.

24 490. Upon information and belief, these representations made by the Innovator and Brand
 25 Defendants were false at the time that they were made, and the Innovator and Brand Defendants
 26 knew or should have known that they were false.

27 491. Because of what the Innovator and Brand Defendants knew or should have known, as
 28 described above, they failed to exercise reasonable care or competence in making these
 misrepresentations.

492. The Innovator and Brand Defendants knew or should have known that the general
 public and the health care community – including Plaintiffs and their prescribing physicians – would

1 not have been aware that their statements about the testing, safety and effectiveness associated with
 2 Propoxyphene Products were false, and would have instead justifiably relied on them, because:

- 3 a. the general public and the health care community did not have access to the
 4 same resources, analysis and knowledge as the Innovator and Brand
 5 Defendants; and
- 6 b. the Innovator and Brand Defendants manufactured, sold and distributed
 7 Propoxyphene Products, and would therefore be assumed to have superior
 8 knowledge about them.

9 493. At all relevant times, Plaintiffs and their prescribing physicians did not, in fact, know
 10 that the Innovator and Brand Defendants' misrepresentations were false.

11 494. Because of what the Innovator and Brand Defendants knew or should have known, as
 12 described above, they failed to exercise reasonable care or competence in making these
 13 misrepresentations.

14 495. Plaintiffs and their prescribing physicians justifiably relied and acted upon the
 15 Innovator and Brand Defendants' misrepresentations, by Plaintiffs' physicians prescribing
 16 Propoxyphene Products, and Plaintiffs purchasing and ingesting Propoxyphene Products.

17 496. Had the Innovator and Brand Defendants not made these misrepresentations:

- 18 a. Plaintiffs' physicians would not have prescribed Propoxyphene Products, and
 19 would have instead prescribed another pain management medication that
 20 neither contained propoxyphene nor involved an increased risk of serious
 21 adverse cardiovascular events that could result in death, or recommended that
 22 Plaintiffs instead take over-the-counter acetaminophen;
- 23 b. Plaintiffs would not have purchased or ingested the Generic Defendants'
 24 Propoxyphene Products; and
- 25 c. Plaintiffs would not have suffered the injuries described above.

26 497. In light of what the Innovator and Brand Defendants knew or should have known, they
 27 should have anticipated that their misrepresentations would likely result in physicians prescribing
 28 Propoxyphene Products, and consumers purchasing and ingesting generic Propoxyphene Products,

1 and, as a direct and proximate result, suffering serious adverse cardiovascular effects that could result
2 in death.

3 498. Plaintiffs' prescription for and purchase and ingestion of Propoxyphene Products, and
4 the injuries described above that followed, were the direct and proximate result of the Innovator and
5 Brand Defendants' misrepresentations.

6 499. By making the misrepresentations described above, the Innovator and Brand
7 Defendants knowingly risked the lives of unsuspecting consumers in order to continue making a
8 profit, and their conduct thus was extreme and outrageous, and warrants an award of punitive
9 damages.

10 500. As a direct and proximate result of the defective and inappropriate warnings and the
11 unreasonably dangerous and defective characteristics of propoxyphene, and the Defendants' failure to
12 comply with federal standards and requirements, Plaintiffs suffered severe and permanent injuries as
13 herein alleged. Plaintiffs endured substantial conscious pain and suffering, both physical and
14 emotional in nature. Plaintiffs incurred significant expenses for medical care and treatment, suffered
15 lost wages and earnings, and were otherwise physically, emotionally, and economically injured.
16 Plaintiffs suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from the
17 Defendants as alleged herein. The injuries and damages alleged herein are permanent and will
18 continue into the future.

19 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble, and
20 punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the
21 Court deems proper.

22
23 **TWENTIETH CAUSE OF ACTION**
24 **FRAUDULENT MISREPRESENTATION AND CONCEALMENT**
(Against Innovator and Brand Defendants)

25 501. Plaintiffs incorporate and adopt by reference each paragraph set forth in this
26 Complaint.

27 502. At all relevant times, the Innovator and Brand Defendants were engaged in the
28 business of researching, designing, manufacturing, testing, studying, labeling, packaging,

1 distributing, selling, supplying, marketing and/or promoting Darvocet and Darvon, brand-name
2 Propoxyphene Products.

3 503. At all relevant times, the Innovator and Brand Defendants had a duty to:

- 4 a. assess, manage and communicate the risks, dangers and adverse effects
5 associated with their Propoxyphene Products to the health care community and
6 the general public, including Plaintiffs and their prescribing physicians; and
7 b. distribute their Propoxyphene Products with adequate information about the
8 appropriate use of the products and their associated risks provided to the
9 general public and the health care community, including Plaintiffs and their
10 prescribing physicians.

11 504. At all relevant times, the Innovator and Brand Defendants knew or should have known
12 that physicians who prescribe drugs to their patients, in making their decisions on what to prescribe,
13 often rely on the statements made about the brand formulations of a drug, and thus that the physicians
14 who prescribed either brand or generic Propoxyphene Products to their patients were relying on the
15 statements that the Innovator and Brand Defendants made about Darvocet and/or Darvon.

16 505. At all relevant times, the Innovator and Brand Defendants knew or should have known
17 that patients who are prescribed a brand formulation of a drug are more likely to purchase the generic
18 than the brand formulation, and thus that patients who were prescribed Darvocet and/or Darvon likely
19 would have instead purchased a generic formulation of Darvocet and/or Darvon.

20 506. Because of this knowledge, the duties of the Innovator and Brand Defendants that are
21 outlined above applied at all relevant times not only to the purchasers of the brand products and their
22 prescribing physicians, but also to the purchasers of generic formulations of those drugs and their
23 prescribing physicians, including Plaintiffs and their prescribing physicians.

24 507. This count applies to the Innovator and Brand Defendants in relation to Plaintiffs'
25 ingestion of generic Propoxyphene Products.

26 508. Before Plaintiffs were injured by ingesting the Generic Defendants' Propoxyphene
27 Products, the Innovator and Brand Defendants knew that:

- 28 a. propoxyphene had not been adequately tested;

- b. Propoxyphene Products were associated with a greatly increased risk of serious adverse cardiovascular events that could result in death, which outweighed their benefit for pain relief;
- c. the risks, and the nature, scope, severity and duration of any serious side effects, were greater with Propoxyphene Products than with other practical, medically feasible and available pain management medications;
- d. Propoxyphene Products were unreasonably dangerous to the health of patients suffering from pain; and
- e. Propoxyphene Products were no more effective for pain management than other available, practical, and medically-feasible alternate pain management medications, such as over-the-counter acetaminophen (brand name Tylenol), which posed less risk.

509. More specifically, the Innovator and Brand Defendants knew that:

- a. In 1971, six out of seven trials demonstrated that while propoxyphene alone was not significantly superior to placebo in managing pain, acetaminophen alone was;
- b. In 1978, the Health Research Group filed a petition with the FDA requesting the recall of Darvon based on its claim that it was a dangerous drug of questionable effectiveness, and subsequently submitted studies supporting that propoxyphene could be toxic to the cardiovascular system;
- c. In January 2005, health officials in Great Britain called for a phased withdrawal of propoxyphene-containing products because they were concerned about the cardiac effects associated with their use and were unable to identify any patient group in whom the risk benefit ratio may be positive;
- d. In June 2009, the European Medicines Agency recommended withdrawal across the European Union of marketing authorizations for propoxyphene-containing medications because available evidence suggested that acetaminophen alone was as effective as an acetaminophen-propoxyphene combination, and that the benefits of medicines containing propoxyphene, either alone or in combination, did not outweigh their risks.
- e. In 2009, the FDA ordered Xanodyne to include a Black Box warning concerning the risk of fatal overdose, and to add warnings to its label about propoxyphene's dangers overall, for elderly patients, and in terms of its potential for abuse and dependence.
- f. In 2009, the FDA also ordered Xanodyne to conduct clinical studies to assess the potential for cardiotoxicity associated with propoxyphene use, to prepare a MedGuide to highlight important safeguards for use of the drug, and to issue a Public Health Advisory to underscore safety issues.

- 1 g. In July 2009, Xanodyne's study confirmed that propoxyphene can cause
2 significant changes to the heart, even when taken at recommended doses.

3
4 510. Despite what the Innovator and Brand Defendants knew, upon information and belief,
5 the Innovator and Brand Defendants falsely represented to the general public and the health care
6 community in reports, press releases, advertising campaigns, television commercials, print
7 advertisements, billboards, other commercial media, promotional materials, instructional material and
8 labeling that:

- 9 a. propoxyphene had been adequately tested;
10 b. Propoxyphene Products were safe and effective for pain management; and
11 c. Propoxyphene Products were more effective for pain management than other
12 pain management medications.

13 511. Upon information and belief, these representations were all intentionally false and
14 misleading at the time they were made, and the Innovator and Brand Defendants knew that they were
15 false and misleading, and willfully, wantonly and recklessly disregarded that they were false.

16 512. The Innovator and Brand Defendants knew that the general public and the health care
17 community – including Plaintiffs and their prescribing physicians – would not have been aware that
18 their statements about the testing, safety and effectiveness associated with Propoxyphene Products
19 were false, and would have instead justifiably relied on them, because:

- 20 a. the general public and the health care community did not have access to the
21 same resources, analysis and knowledge as the Innovator and Brand
22 Defendants; and
23 b. the Innovator and Brand Defendants manufactured, sold and distributed
24 Propoxyphene Products, and would therefore be assumed to have superior
25 knowledge about them.

26 513. At all relevant times, Plaintiffs and their prescribing physicians did not, in fact, know
27 that the Innovator and Brand Defendants' misrepresentations were false.
28

1 514. The Innovator and Brand Defendants made these material misrepresentations because
2 they wanted the general public and the health care community to rely on them, and wanted to induce
3 medical providers – including Plaintiffs’ treating physicians – to prescribe Propoxyphene Products,
4 and consumers – including Plaintiffs – to request or not resist those prescription.

5 515. Plaintiffs and their prescribing physicians justifiably relied and acted upon the
6 Innovator and Brand Defendants’ misrepresentations, by Plaintiffs’ physicians prescribing
7 Propoxyphene Products, and Plaintiffs requesting or not resisting that prescription.

8 516. Had the Innovator and Brand Defendants not made these misrepresentations:

- 9
- 10 a. Plaintiffs’ physicians would not have prescribed Propoxyphene Products, and
11 would have instead prescribed another pain management medication that
12 neither contained propoxyphene nor involved an increased risk of serious
13 adverse cardiovascular events that could result in death, or recommended that
14 Plaintiffs instead take over-the-counter acetaminophen;
 - 15 b. Plaintiffs would not have purchased or ingested the Generic Defendants’
16 Propoxyphene Products; and
 - 17 c. Plaintiffs would not have suffered the injuries described above.

18 517. In light of what the Innovator and Brand Defendants knew, they had to have known
19 that their misrepresentations would likely result in physicians prescribing Propoxyphene Products,
20 and consumers purchasing and ingesting generic Propoxyphene Products, and, as a direct and
21 proximate result, suffering serious adverse cardiovascular effects that could result in death.

22 518. Plaintiffs’ prescription for and purchase and ingestion of Propoxyphene Products, and
23 the injuries described above that followed, were the direct and proximate result of the Innovator and
24 Brand Defendants’ knowing misrepresentations.

25 519. By making the misrepresentations described above, the Innovator and Brand
26 Defendants knowingly risked the lives of unsuspecting consumers in order to continue making a
27 profit, and their conduct thus was extreme and outrageous, and warrants an award of punitive
28 damages.

1 520. Upon information and belief, Plaintiffs allege that Defendants actively and
2 fraudulently concealed information in Defendants' exclusive possession regarding the hazards
3 associated with the Propoxyphene Products with the purpose of preventing consumers, such as
4 Plaintiffs, from discovery these hazards.

5 521. As a direct and proximate result of the defective manufacturing and the unreasonably
6 dangerous and defective characteristics of the Propoxyphene Products and the Defendants' failure to
7 comply with federal standards and requirements, the Plaintiffs suffered severe and permanent
8 injuries. Plaintiffs endured substantial conscious pain and suffering, both physical and emotional in
9 nature. Plaintiffs incurred significant expenses for medical care and treatment, suffered lost wages
10 and earnings, and was otherwise physically, emotionally, and economically injured. Plaintiffs
11 suffered severe pecuniary loss. Plaintiffs seek actual and punitive damages from the Defendants as
12 alleged herein. The injuries and damages alleged herein are permanent and will continue into the
13 future.

14 522. Defendants acted willfully or with gross negligence indicating a wanton disregard for
15 the rights of Plaintiffs and others, rendering Defendants liable to Plaintiffs for punitive damages. The
16 aforesaid conduct of the Defendants was committed with knowing, conscious, and deliberate
17 disregard for the rights and safety of consumers, including Plaintiffs herein, thereby entitled Plaintiffs
18 to punitive damages in an amount appropriate to punish the Defendants and deter them from similar
19 conduct in the future.

20 523. The aforesaid conduct of the Defendants was committed with knowing, conscious, and
21 deliberate disregard for the rights and safety of consumers, including Plaintiffs herein, thereby
22 entitling Plaintiffs to punitive damages in an amount appropriate to punish the Defendants and deter
23 them from similar conduct in the future.

24 WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble, and
25 punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the
26 Court deems proper.

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PUNITIVE DAMAGE

524. At all times material hereto, the Defendants knew or should have known that the administration of propoxyphene could result in the development of including, but not limited to, an increased risk of serious adverse cardiovascular events that could result in death.

525. At all times material hereto, the Defendants attempted to misrepresent and did misrepresent facts concerning the safety of propoxyphene and products containing propoxyphene.

526. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiffs herein, concerning the safety of propoxyphene.

527. At all times material hereto, the Defendants knew and recklessly disregarded the fact that propoxyphene and products containing propoxyphene could result in the development of including, but not limited to, an increased risk of serious adverse cardiovascular events that could result in death.

528. Notwithstanding the foregoing, the Defendants continued to aggressively market products containing propoxyphene to consumers, including Plaintiffs herein, without disclosing the fact that administration of propoxyphene could result in the development of including, but not limited to, an increased risk of serious adverse cardiovascular events that could result in death.

529. The Defendants knew of the defective and unreasonably dangerous nature of products containing propoxyphene as set forth herein, but continued to design, develop, manufacture, market, distribute, and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiffs herein, in conscious and/or negligent disregard of the foreseeable risks including, adverse cardiovascular events that could result in death.

530. Defendants intentionally concealed and/or recklessly failed to disclose to the public, including Plaintiffs herein, the potentially life threatening side effects of the administration of propoxyphene in order to ensure continued and increased sales.

531. The Defendants' intentional and/or reckless failure to disclose information deprived Plaintiffs of necessary information to enable Plaintiffs and their healthcare providers to weigh the true risks of using propoxyphene against the benefits.

1 532. As a direct and proximate result of the Defendants' conscious and deliberate disregard
2 for the rights and safety of consumers such as the Plaintiffs, and the unreasonably dangerous and
3 defective characteristics of propoxyphene, and the Defendants' failure to comply with federal
4 standards and requirements, Plaintiffs suffered severe and permanent injuries, and other neurological
5 and movement disorders.

6 533. Plaintiffs incurred significant expenses for medical care and treatment, suffered lost
7 wages and earnings, and were otherwise economically injured. Plaintiffs suffered severe pecuniary
8 loss. Plaintiffs seek actual and punitive damages from the Defendants as alleged herein.

9 534. The aforesaid conduct of the Defendants was committed with knowing, conscious, and
10 deliberate disregard for the rights and safety of consumers, including Plaintiffs herein, thereby
11 entitling Plaintiffs to punitive damages in an amount appropriate to punish the Defendants and deter
12 them from similar conduct in the future.

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PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, as follows:

1. For general damages according to proof;
2. For specific damages, according to proof;
3. For punitive/exemplary damages;
4. For Plaintiffs' costs incurred herein;
5. For the costs of suit; and
6. For pre-judgment interest;
7. For such other and further relief as the Court may deem just and proper.

Respectfully submitted,

DATED: November 9, 2012

SIZEMORE LAW FIRM

By _____
J. PAUL SIZEMORE
Attorneys for Plaintiffs

DEMAND FOR JURY TRIAL

Plaintiffs respectfully demand a trial by jury on all claims.

Respectfully submitted,

DATED: November 9, 2012

SIZEMORE LAW FIRM

By _____
J. PAUL SIZEMORE
Attorneys for Plaintiffs